UNITEDHEALTHCARE® COMMUNITY PLAN: RADIOLOGY IMAGING COVERAGE DETERMINATION GUIDELINE

Adult Oncology Imaging Guidelines (For Ohio Only)

V1.0.2026

Guideline Number: CSRAD010OH.E

Effective Date: February 3, 2026

Application (for Ohio Only)

This Medical Policy only applies to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

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Related Community Plan Policies

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Related Community Plan Policies

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Related Community Plan Policies

Related Community Plan Policies

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Guideline Development (Preface-1)

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Guideline Development (Preface-1.1)

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- These evidence-based, proprietary clinical guidelines evaluate a range of advanced imaging and procedures, including NM, US, CT, MRI, PET, Radiation Oncology, Sleep Studies, as well as Cardiac, musculoskeletal and Spine interventions.
- UnitedHealthcare reserves the right to change and update the guidelines. The guidelines undergo a formal review annually. These clinical guidelines are based on current evidence supported by major national and international association and society guidelines and criteria, peer-reviewed literature, major treatises as well as, input from health plans, and practicing academic and community-based physicians.
- These guidelines are not intended to supersede or replace sound medical judgment, but instead, should facilitate the identification of the most appropriate imaging or other designated procedure given the individual's clinical condition. These guidelines are written to cover medical conditions as experienced by the majority of individuals. However, these guidelines may not be applicable in certain clinical circumstances, and physician judgment can override the guidelines.
- These guidelines provide evidence-based, clinical benefits with a focus on health care quality and patient safety.
- Clinical decisions, including treatment decisions, are the responsibility of the individual and his/her provider. Clinicians are expected to use independent medical judgment, which takes into account the clinical circumstances to determine individual management decisions.

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Benefits, Coverage Policies, and Eligibility Issues (Preface-2)

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Benefits, Coverage Policies, and Eligibility Issues (Preface-2.1)
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Benefits, Coverage Policies, and Eligibility Issues (Preface-2.1)

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Investigational and Experimental Studies

- Certain studies, treatments, procedures, or devices may be considered experimental, investigational, or unproven for any condition, illness, disease, injury being treated if one of the following is present:
  - if there is a paucity of supporting evidence;
  - if the evidence has not matured to exhibit improved health parameters;
  - if clinical utility has not been demonstrated in any condition; OR
  - if the study, treatment, procedure, or device lacks a collective opinion of support
- Supporting evidence includes standards that are based on credible scientific evidence published in peer-reviewed medical literature (such as well conducted randomized clinical trials or cohort studies with a sample size of sufficient statistical power) generally recognized by the relevant medical community. Collective opinion of support includes physician specialty society recommendations and the views of physicians practicing in relevant clinical areas when physician specialty society recommendations are not available.

Clinical and Research Trials

- Similar to investigational and experimental studies, clinical trial imaging requests are reviewed to determine whether they meet these evidence-based clinical guidelines.
- Imaging studies which are inconsistent with established clinical standards, or are requested for data collection and not used in direct clinical management are not supported.

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References (Preface-2)

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1. Coverage of Clinical Trials under the Patient Protection and Affordable Care Act; 42 U.S.C.A. § 300gg-8

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Clinical Information (Preface-3.1)

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Clinical Documentation and Age Considerations

- These clinical guidelines use an evidence-based approach to determine the most appropriate procedure for each individual, at the most appropriate time in the diagnostic and treatment cycle. These clinical guidelines are framed by:
  - clinical presentation of the individual, rather than the studies requested
  - adequate clinical information that must be submitted to UnitedHealthcare in order to establish medical necessity for advanced imaging or other designated procedures includes, but is not limited to, the following:
    - Pertinent clinical evaluation since the onset or change in symptoms including a detailed history, physical examination, appropriate laboratory studies, and appropriate prior imaging studies.
      - Condition-specific guideline sections may describe additional clinical information which is required for a pertinent clinical evaluation.
      - The Spine and Musculoskeletal guidelines require x-ray studies from when the current episode of symptoms has started or changed.
      - Advanced imaging or other designated procedures should not be ordered prior to clinical evaluation of an individual by the physician treating the individual. This may include referral to a consultant specialist who will make further treatment decisions.
      - Other meaningful technological contact (telehealth visit, telephone or video call, electronic mail or messaging) since the onset or change in symptoms by an established individual can serve as a pertinent clinical evaluation.
        - Some conditions may require a face-to-face evaluation as discussed in the applicable condition-specific guideline sections.
    - A recent clinical evaluation may be unnecessary if the individual is undergoing a guideline-supported, scheduled follow-up imaging or other designated procedural evaluation. Exceptions due to routine surveillance indications are addressed in the applicable condition-specific guideline sections.
  - the evidence-based approach to determine the most appropriate procedure for each individual requires submission of medical records pertinent to the requested imaging or other designated procedures.
- Many conditions affecting the pediatric population are different diagnoses than those occurring in the adult population. For those diseases which occur in both pediatric and adult populations, minor differences may exist in management due to individual

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age, comorbidities, and differences in disease natural history between children and adults.
  - Individuals who are 18 years old or younger should be imaged according to the Pediatric Imaging Guidelines if discussed in the condition-specific guideline sections. Any conditions not specifically discussed in the Pediatric Imaging Guidelines should be imaged according to the General Imaging Guidelines. Individuals who are >18 years old should be imaged according to the General Imaging Guidelines, except where directed otherwise by a specific guideline section.

General Imaging Information

- "Standard" or "conventional" imaging is most often performed in the initial and subsequent evaluations of malignancy. Standard or conventional imaging includes plain film, CT, MRI, or US.
  - Often, further advanced imaging is needed when initial imaging, such as ultrasound, CT, or MRI does not answer the clinical question. Uncertain, indeterminate, inconclusive, or equivocal may describe these situations.
- Appropriate use of contrast is a very important component of evidence-based advanced imaging use.
  - The appropriate levels of contrast for an examination (i.e., without contrast, with contrast, without and with contrast) is determined by the evidence-based guidance reflected in the condition-specific guideline sections.
  - If, during the performance of a non-contrast imaging study, there is the unexpected need to use contrast in order to evaluate a possible abnormality, then that is appropriate.

Ultrasound

- Diagnostic ultrasound uses high-frequency sound waves to evaluate soft tissue structures and vascular structures utilizing grey scale and Doppler techniques.
- Ultrasound allows for dynamic real-time imaging at the bedside.
  - Ultrasound is limited in areas where there is dense bone or other calcification.
  - Ultrasound also has a relatively limited imaging window so may be of limited value in evaluating very large abnormalities.
  - In general, ultrasound is highly operator-dependent, and proper training and experience are required to perform consistent, high-quality evaluations.
- Indications for ultrasound may include, but are not limited to, the following:
  - Obstetric and gynecologic imaging
  - Soft tissue and visceral imaging of the chest, abdomen, pelvis, and extremities
  - Brain and spine imaging when not obscured by dense bony structures
  - Vascular imaging when not obscured by dense bony structures
  - Procedural guidance when not obscured by dense bony structures

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- Initial evaluation of ill-defined soft tissue masses or fullness and differentiating adenopathy from mass or cyst. Prior to advanced imaging, ultrasound can be very beneficial in selecting the proper modality, body area, image sequences, and contrast level that will provide the most definitive information for the individual.

- More specific guidance for ultrasound usage, including exceptions to this general guidance, can be found throughout the condition-specific guidelines.

Computed Tomography (CT)

- The AMA CPT® manual does not describe nor assign any minimum or maximum number of sequences for any CT study. CT imaging protocols are often influenced by the individual's clinical situation and additional sequences are not uncommon. There are numerous CT protocols that may be performed to evaluate specific clinical questions, and this technology is constantly undergoing development.
- CT utilizes ionizing radiation to create cross-sectional and volumetric images of the body.
  - Advantages over ultrasound include a much larger field of view and faster completion time in general. Disadvantages compared to ultrasound include lack of portability and exposure to ionizing radiation.
  - Advantages over MRI include faster imaging and a more spacious scanner area limiting claustrophobia. Disadvantages compared to MRI include decreased soft tissue definition, especially with non-contrast imaging, and exposure to ionizing radiation.
- CT can be performed without, with, or without and with intravenous (IV) contrast depending on the clinical indication and body area.
  - In general, non-contrast imaging is appropriate for evaluating structures with significant tissue density differences such as lung parenchyma and bony structures, or when there is a contraindication to contrast.
  - In general, CT with contrast is the most common level of contrast and can be used when there is need for improved vascular or soft tissue resolution, including better characterization of known or suspected malignancy, as well as infectious and inflammatory conditions.
  - CT without and with contrast has a limited role as the risks of doubling the ionizing radiation exposure rarely outweigh the benefits of multiphasic imaging, though there are some exceptions which include, but are not limited to, the following:
    - Characterization of a mass
    - Characterization of arterial and venous anatomy
    - CT with contrast may be used to better characterize findings on a very recent (within two weeks) inconclusive non-contrast CT where the guidelines would support CT without and with contrast.
  - More specific guidance for CT contrast usage, including exceptions to this general guidance, can be found throughout the condition-specific guidelines.

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- Shellfish allergy:
  - It is commonly assumed that an allergy to shellfish indicates iodine allergy, and that this implies an allergy to iodinated contrast media used with CT. However, this is NOT true. Shellfish allergy is due to tropomyosins. Iodine plays no role in these allergic reactions. Allergies to shellfish do not increase the risk of reaction to iodinated contrast media any more than that of other allergens.
- Enteric contrast (oral or rectal) is sometimes used in abdominal imaging. There is no specific CPT® code which refers to enteric contrast.
- The appropriate contrast level and anatomic region in CT imaging is specific to the clinical indication, as listed in the condition-specific guideline sections.
- CT should not be used to replace MRI in an attempt to avoid sedation unless it is listed as a recommended study in the appropriate condition-specific guideline.
- There are significant potential adverse effects associated with the use of iodinated contrast media. These include hypersensitivity reactions, thyroid dysfunction, and contrast-induced nephropathy (CIN). Individuals with impaired renal function are at increased risk for CIN.
- Both contrast CT and MRI are considered to have the same risk profile with renal failure (GFR <30 mL/min).
- The use of CT contrast should proceed with caution in pregnant and breastfeeding individuals. There is a theoretical risk of contrast toxicity to the fetal and infant thyroid. The procedure can be performed if the specific need for that contrast-enhanced procedure outweighs risk to the fetus. Breastfeeding individuals may reduce this risk by choosing to pump and discard breast milk for 12-24 hours after the contrast injection.
- CT without contrast is medically necessary if clinical criteria for CT with contrast are met AND the individual has/is:
  - elevated blood urea nitrogen (BUN) and/or creatinine
  - renal insufficiency
  - allergies to iodinated contrast
  - thyroid disease which could be treated with I-131
  - diabetes
  - very elderly
  - urgent or emergent settings due to availability
  - trauma
- CT is superior to other imaging modalities in certain conditions including, but not limited to, the following:
  - Screening following trauma
  - Imaging pulmonary disease
  - Imaging abdominal and pelvic viscera
  - Imaging of complex fractures

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  - Evaluation of inconclusive findings on Ultrasound or MRI, or if there is a contraindication to MRI
- More specific guidance for CT usage, including exceptions to this general guidance, can be found throughout the condition-specific guidelines.

Magnetic Resonance Imaging (MRI)

- The AMA CPT® manual does not describe nor assign any minimum or maximum number of sequences for any MRI study. MRI protocols are often influenced by the individual's clinical situation and additional sequences are not uncommon. There are numerous MRI sequences that may be performed to evaluate specific clinical questions, and this technology is constantly undergoing development.
- Magnetic Resonance Imaging (MRI) utilizes the interaction between the intrinsic radiofrequency of certain molecules in the body (hydrogen in most cases) and a strong external magnetic field.
  - MRI is often superior for advanced imaging of soft tissues and can also define physiological processes in some instances (e.g., edema, loss of circulation [AVN], and increased vascularity [tumors]).
  - MRI does not use ionizing radiation and even non-contrast images have much higher soft tissue definition than CT or Ultrasound.
  - MRI typically takes much longer than either CT or Ultrasound, and for some individuals may require sedation. It is also much more sensitive to individual motion that can degrade image quality than either CT or Ultrasound.
- MRI Breast and MRI Chest are not interchangeable, as they focus detailed sequences on different adjacent body parts.
- MRI may be utilized either as the primary advanced imaging modality, or when further definition is needed based on CT or ultrasound imaging.
- Most orthopedic and dental implants are not magnetic. These include hip and knee replacements; plates, screws, and rods used to treat fractures; and cavity fillings. Yet, all of these metal implants can distort the MRI image if near the part of the body being scanned.
  - Other implants, however, may have contraindications to MRI. These include the following:
    - Pacemakers
    - ICD or heart valves
    - Metal implants in the brain
    - Metal implants in the eyes or ears
    - Infusion catheters and bullets or shrapnel
  - CT can therefore be an alternative study to MRI in these scenarios.
- The contrast level and anatomic region in MRI imaging is specific to the clinical indication, as listed in the specific guideline sections.

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- MRI utilizing Xenon Xe 129 (CPT® C9791) for contrast is considered investigational and experimental at this time. MRI with or with and without contrast in these guidelines refers to MRI utilizing gadolinium for contrast.
- MRI is commonly performed without, without and with contrast.
  - Non-contrast imaging offers excellent tissue definition.
  - Imaging without and with contrast is commonly used when needed to better characterize tissue perfusion and vascularization.
    - Most contrast is gadolinium based and causes T2 brightening of the vascular and extracellular spaces.
    - Some specialized gadolinium and non-gadolinium contrast agents are available, and most commonly used for characterizing liver lesions.
  - MRI with contrast only is rarely appropriate and is usually used to better characterize findings on a recent inconclusive non-contrast MRI, commonly called a completion study.
  - MRI contrast is relatively contraindicated in pregnant individuals.
  - More specific guidance for MRI contrast usage, including exceptions to this general guidance, can be found throughout the condition-specific guidelines.
- MRI may be preferred in individuals with renal failure and in individuals allergic to intravenous CT contrast.
  - Both contrast CT and MRI are considered to have the same risk profile with renal failure (GFR <30 mL/min).
  - Gadolinium can cause Nephrogenic Systemic Fibrosis (NSF). The greater the exposure to gadolinium in individuals with a low GFR (especially if on dialysis), the greater the chance of individuals developing NSF.
  - Multiple studies have demonstrated potential for gadolinium deposition following the use of gadolinium-based contrast agents (GBCAs) for MRI studies. The U.S. Food and Drug Administration (FDA) has noted that there is currently no evidence to suggest that gadolinium retention in the brain is harmful and restricting gadolinium-based contrast agents (GBCAs) use is not warranted at this time. It has been recommended that GBCA use should be limited to circumstances in which additional information provided by the contrast agent is necessary and the necessity of repetitive MRIs with GBCAs should be assessed.
- A CT is medically necessary in place of an MRI when clinical criteria are met for MRI AND there is a contraindication to having an MRI (pacemaker, ICD, insulin pump, neurostimulator, etc.).
  - When replacing MRI with CT, contrast level matching should occur as follows:
    - MRI without contrast → CT without contrast
    - MRI without and with contrast → CT with contrast or CT without and with contrast
- The following situations may impact the appropriateness for MRI and/or MR contrast:

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  - Caution should be taken in the use of gadolinium in individuals with renal failure.
  - The use of gadolinium contrast agents is relatively contraindicated during pregnancy unless the specific need for that procedure outweighs risk to the fetus.
  - MRI can be performed for non-ferromagnetic body metals (i.e., titanium), although some imaging facilities will consider it contraindicated if recent surgery, regardless of the metal type.
- MRI should not be used as a replacement for CT for the sole reason of avoidance of ionizing radiation when MRI is not supported in the condition-based guidelines, since it does not solve the problem of overutilization.
- MRI is superior to other imaging modalities in certain conditions including, but not limited to, the following:
  - Imaging the brain and spinal cord
  - Characterizing visceral and musculoskeletal soft tissue masses
  - Evaluating musculoskeletal soft tissues including ligaments and tendons
  - Evaluating inconclusive findings on ultrasound or CT
  - Individuals who are pregnant or have high radiation sensitivity
  - Suspicion, diagnosis, or surveillance of infections
- More specific guidance for MRI usage, including exceptions to this general guidance, can be found throughout the condition-specific guidelines.

Positron Emission Tomography (PET)

- PET is a nuclear medicine study that uses a positron emitting radiotracer to create cross-sectional and volumetric images based on tissue metabolism.
- Conventional imaging (frequently CT, sometimes MRI or bone scan) of the affected area(s) drives much of initial and restaging and surveillance imaging for malignancy and other chronic conditions. PET is not medically necessary for surveillance imaging unless specifically stated in the condition-specific guideline sections.
- PET/MRI is generally not supported, see **PET-MRI (Preface-5.3)**.
- PET is rarely performed as a single modality, but is typically performed as a combined PET/CT.
  - The unbundling of PET/CT into separate PET and diagnostic CT CPT® codes is not supported, because PET/CT is done as a single study.
- PET/CT lacks the tissue definition of CT or MRI, but is fairly specific for metabolic activity based on the radiotracer used.
- Indications for PET/CT may include the following:
  - Oncologic Imaging for evaluation of tumor metabolic activity
  - Cardiac Imaging for evaluation of myocardial metabolic activity
  - Brain Imaging for evaluation of metabolic activity for procedural planning
- More specific guidance for PET usage, including exceptions to this general guidance, can be found throughout the condition-specific guidelines.

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Overutilization of Advanced Imaging

- A number of reports describe overutilization in many areas of advanced imaging and other procedures, which may include the following:
  - High-level testing without consideration of less invasive, lower cost options which may adequately address the clinical question at hand
  - Excessive radiation and costs with unnecessary testing
  - Defensive medical practice
  - CT without and with contrast (so called "double contrast studies") requests, which have few current indications
  - MRI requested in place of CT to avoid radiation without considering the primary indication for imaging
  - Adult CT settings and protocols used for smaller people and children
  - Unnecessary imaging procedures when the same or similar studies have already been conducted
- A review of the imaging or other relevant procedural histories of all individuals presenting for studies has been recognized as one of the more important processes that can be significantly improved. By recognizing that a duplicate or questionably medically necessary imaging study has been ordered for individuals, it may be possible to avoid exposing them to unnecessary risks. To avoid these unnecessary risks, the precautions below should be considered:
  - The results of initial diagnostic tests or radiologic studies to narrow the differential diagnosis should be obtained prior to performing further tests or radiologic studies.
  - The clinical history should include a potential indication such as a known or suspected abnormality involving the body part for which the imaging study is being requested. These potential indications are addressed in greater detail within the applicable guidelines.
  - The results of the requested imaging procedures should be expected to have an impact on individual management or treatment decisions.
  - Repeat imaging studies are not generally necessary unless there is evidence of disease progression, recurrence of disease, and/or the repeat imaging will affect an individual’s clinical management.
- Pre-operative imaging/pre-surgical planning imaging/pre-procedure imaging is not medically necessary if the surgery/procedure is not medically necessary. Once the procedure has been approved or if the procedure does not require prior authorization, the appropriate pre-procedural imaging may be approved.

Health Equity Considerations

Health equity is the highest level of health for all individuals; health inequity is the avoidable difference in health status or distribution of health resources due to the social

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conditions in which individuals are born, grow, live, work, and age. Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include the following: safe housing, transportation, and neighborhoods; racism, discrimination, and violence; education, job opportunities, and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

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Coding Issues (Preface-4)

Guideline

3D Rendering (Preface-4.1)
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3D Rendering (Preface-4.1)

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CPT® 76376 and CPT® 76377

- Both codes require concurrent supervision of the image post-processing 3D manipulation of the volumetric data set and image rendering.
  - Concurrent supervision is defined as active physician participation in and monitoring of the reconstruction process including design of the anatomic region that is to be reconstructed; determination of the tissue types and actual structures to be displayed (e.g., bone, organs, and vessels); determination of the images or cine loops that are to be archived; and, monitoring and adjustment of the 3D work product. The American College of Radiology (ACR) recommends that it is best to document the physician's supervision or participation in the 3D reconstruction of images.
- These two codes differ in the need for and use of an independent workstation for post-processing.
  - CPT® 76376 reports procedures not requiring image post-processing on an independent workstation.
  - CPT® 76377 reports procedures that require image post-processing on an independent workstation.
- These 3D rendering codes should not be used for 2D reformatting.
- Two-dimensional reconstruction (e.g., reformatting an axial scan into the coronal plane) is now included in all cross-sectional imaging base codes and is not separately reimbursable.
- The codes used to report 3D rendering for ultrasound and echocardiography are also used to report the 3D post processing work on CT, MRI, and other tomographic modalities.
- Providers may be required to obtain prior authorization on these 3D codes even if prior authorization is not required for the echocardiography and/or ultrasound procedure codes. It may appear that UnitedHealthcare pre-authorizes echocardiography and/or ultrasound when, in fact, it may only be the 3D code that needs the prior authorization.
- CPT® codes for 3D rendering should not be billed in conjunction with computer-aided detection (CAD), MRA, CTA, nuclear medicine SPECT studies, PET, PET/CT, stereotactic localization (CPT® 77011 or CPT® 70486 if used), Mammogram, MRI Breast, US Breast, CT Colonography (virtual colonoscopy), Cardiac MRI, Cardiac CT, or Coronary CTA studies.

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- CPT® 76377 (3D rendering requiring image post-processing on an independent workstation) or CPT® 76376 (3D rendering not requiring image post-processing on an independent workstation) can be considered in the following clinical scenarios:
  - Bony conditions:
    - Evaluation of congenital skull abnormalities in newborns, infants, and toddlers (usually for pre-operative planning)
    - Complex fractures (comminuted or displaced)/dislocations of any joint (for pre-operative planning when conventional imaging is insufficient)
    - Spine fractures, pelvic/acetabulum fractures, intra-articular fractures (for pre-operative planning when conventional imaging is insufficient)
    - Pre-operative planning for other complex surgical cases
    - Complex facial fractures
  - Pre-operative planning for other complex surgical cases
  - Cerebral angiography
  - Pelvis conditions:
    - Uterine intra-cavitary lesion when initial US is equivocal: See **Abnormal Uterine Bleeding (AUB) (PV-2.1)** and **Leiomyoma/Uterine Fibroids (PV-12.1)** in the Pelvis Imaging Guidelines.
    - Hydrosalpinxes or peritoneal cysts when initial US is indeterminate: See **Complex Adnexal Masses (PV-5.3)** in the Pelvis Imaging Guidelines.
    - Lost IUD (inability to feel or see IUD string) with initial US: See **Intrauterine Device (PV-10.1)** in the Pelvis Imaging Guidelines.
    - Uterine anomalies with initial US: See **Uterine Anomalies (PV-14.1)** in the Pelvis Imaging Guidelines.
    - Infertility: See **Initial Infertility Evaluation, Female (PV-9.1)** in the Pelvis Imaging Guidelines.
  - Abdomen conditions:
    - CT Urogram: See **Hematuria and Hydronephrosis (AB-39)** in the Abdomen Imaging Guidelines.
    - MRCP: See **MR Cholangiopancreatography (MRCP) (AB-27)** in the Abdomen Imaging Guidelines.

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CT-, MR-, or Ultrasound-Guided Procedures (Preface-4.2)

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- CT-, MR-, and Ultrasound-guidance procedure codes contain all of the imaging necessary to guide a needle or catheter. It is inappropriate to routinely bill a diagnostic procedure code in conjunction with a guidance procedure code.
- Imaging studies performed as part of a CT-, MR-, or Ultrasound-guided procedure should be reported using the CPT® codes in the following table:

TABLE: Imaging Guidance Procedure Codes

CPT®	Description
19085	Biopsy, breast, with placement of breast localization device(s), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including MR guidance
19086	Biopsy, breast, with placement of breast localization device(s), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including MR guidance
75989	Imaging guidance for percutaneous drainage with placement of catheter (all modalities)
76942	Ultrasonic guidance for needle placement
77011	CT guidance for stereotactic localization
77012	CT guidance for needle placement
77013	CT guidance for, and monitoring of parenchymal tissue ablation
77021	MR guidance for needle placement
77022	MR guidance for, and monitoring of parenchymal tissue ablation

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CPT® 19085 and CPT® 19086

- The proper way to bill an MRI-guided breast biopsy is CPT® 19085 (Biopsy, breast, with placement of breast localization device(s), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including MR guidance). Additional lesions should be billed using CPT® 19086.
  - **CPT® 77021** (MR guidance for needle placement) is not an appropriate code for a breast biopsy.

CPT® 75989

- This code is used to report imaging guidance for a percutaneous drainage procedure in which a catheter is left in place.
- This code can be used to report whether the drainage catheter is placed under fluoroscopy, Ultrasound-, CT-, or MR-guidance modality.

CPT® 77011

- A stereotactic CT localization scan is frequently obtained prior to sinus surgery. The dataset is then loaded into the navigational workstation in the operating room for use during the surgical procedure. The information provides exact positioning of surgical instruments with regard to the individual's 3D CT images.
- In most cases, the pre-operative CT is a technical-only service that does not require interpretation by a radiologist.
  - The imaging facility should report CPT® 77011 when performing a scan not requiring interpretation by a radiologist.
  - If a diagnostic scan is performed and interpreted by a radiologist, the appropriate diagnostic CT code (e.g., CPT® 70486) should be used.
  - It is not appropriate to report both CPT® 70486 and CPT® 77011 for the same CT stereotactic localization imaging session.
  - 3D Rendering (CPT® 76376 or CPT® 76377) should not be reported in conjunction with CPT® 77011 (or CPT® 70486 if used). The procedure inherently generates a 3D dataset.

CPT® 77012 (CT) and CPT® 77021 (MR)

- These codes are used to report imaging guidance for needle placement during biopsy, aspiration, and other percutaneous procedures.
- They represent the radiological supervision and interpretation of the procedure and are often billed in conjunction with surgical procedure codes.
  - For example, CPT® 77012 is reported when CT guidance is used to place the needle for a conventional arthrogram.
  - Only codes representing percutaneous surgical procedures should be billed with CPT® 77012 and CPT® 77021. It is inappropriate to use with surgical codes for open, excisional, or incisional procedures.

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- **CPT® 77021** (MR guidance for needle placement) is not an appropriate code for breast biopsy.
  - CPT® 19085 would be appropriate for the first breast biopsy site and CPT® 19086 would be appropriate for additional concurrent biopsies.

CPT® 77013 (CT) and CPT® 77022 (MR)

- These codes include the initial guidance to direct a needle electrode to the tumor(s), monitoring for needle electrode repositioning within the lesion, and as necessary for multiple ablations to coagulate the lesion and confirmation of satisfactory coagulative necrosis of the lesion(s) and comparison to pre-ablation images.
  - **NOTE:** CPT® 77013 should only be used for non-bone ablation procedures.
    - CPT® 20982 includes CT guidance for bone tumor ablations.
  - Only codes representing percutaneous surgical procedures should be billed with CPT® 77013 and CPT® 77022. It is inappropriate to use with surgical codes for open, excisional, or incisional procedures.
- CPT® 77012 and CPT® 77021 (as well as guidance codes CPT® 76942 [US], and CPT® 77002 - CPT® 77003 [fluoroscopy]) describe radiologic guidance by different modalities.
  - Only one unit of any of these codes should be reported per individual encounter (date of service). The unit of service is considered to be the individual encounter, not the number of lesions, aspirations, biopsies, injections, or localizations.

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Unlisted Procedures/Therapy Treatment Planning (Preface-4.3)

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Unlisted Procedures

CPT ®	Description
76497	Unlisted CT procedure (e.g., diagnostic or interventional)
76498	Unlisted MR procedure (e.g., diagnostic or interventional)
78999	Unlisted procedure, diagnostic nuclear medicine

- For general information related to unlisted procedures, please refer to **Management of Unlisted Codes**.
- These unlisted codes should be reported whenever a diagnostic or interventional CT or MR study is performed in which an appropriate anatomic site-specific code is not available.
  - A Category III code that describes the procedure performed must be reported rather than an unlisted code if one is available.
- CPT® 76497 or CPT® 76498 (Unlisted CT or MRI procedure) is medically necessary in the following clinical scenarios:
  - Studies done for navigation and planning for neurosurgical procedures (i.e., Stealth or Brain Lab Imaging)
  - Custom joint arthroplasty planning (not as an alternative recommendation): See **Osteoarthritis (MS-12.1)** in the Musculoskeletal Imaging Guidelines.
  - Any procedure/surgical planning if thinner cuts or different positional acquisition (than those on the completed diagnostic study) are needed. These could include navigational bronchoscopy: See **Navigational Bronchoscopy and Biopsy (CH-1.7)** in the Chest Imaging Guidelines.

Therapy Treatment Planning

- Radiation Therapy Treatment Planning: See **Unlisted Procedure Codes in Oncology (ONC-1.5)** in the Oncology Imaging Guidelines.

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CPT® 76380 Limited or Follow-up CT (Preface-4.5)

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- CPT® 76380 describes a limited or follow-up CT scan. The code is used to report any CT scan, for any given area of the body, in which the work of a full diagnostic code is not performed.
- Common examples include, but are not limited to, the following:
  - Limited sinus CT imaging protocol
  - Limited or follow-up slices through a known pulmonary nodule
  - Limited slices to assess a non-healing fracture (such as the clavicle)
- Limited CT (CPT® 76380) is not medically necessary for treatment planning purposes. See **Unlisted Procedure Codes in Oncology (ONC-1.5)** in the Oncology Imaging Guidelines.
- It is inappropriate to report CPT® 76380, in conjunction with other diagnostic CT codes, to cover 'extra slices' in certain imaging protocols.
  - There is no specific number of sequences or slices defined in any CT CPT® code definition.
  - The AMA, in *CPT® 2019*, does not describe nor assign any minimum or maximum number of sequences or slices for any CT study.
    - A few additional slices or sequences are not uncommon.
    - CT imaging protocols are often influenced by the individual's clinical situation. Sometimes the protocols require more time and sometimes less.

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SPECT/CT Imaging (Preface-4.6)

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- SPECT/CT involves SPECT (Single Photon Emission Computed Tomography) nuclear medicine imaging and CT for optimizing location, accuracy, and attenuation correction and combines functional and anatomic information.
  - Common studies using this modality include ^{123}I- or ^{131}I-Metaiodobenzylguanidine (MIBG) and octreotide scintigraphy for neuroendocrine tumors.
- Hybrid Nuclear/CT scan can be reported as CPT® 78830 (single area and single day), CPT® 78831 (2 or more days), or CPT® 78832 (2 areas with one day and 2-day study).
- CPT® 78072 became effective January 1, 2013 for SPECT/CT parathyroid nuclear imaging.

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CPT® 76140 Interpretation of an Outside Study (Preface-4.7)

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- It is inappropriate to use diagnostic imaging codes for interpretation of a previously performed exam that was completed at another facility.
  - If the outside exam is being used for comparison with a current exam, the diagnostic code for the current examination includes comparison to the prior study.
  - CPT® 76140 is the appropriate code to use for an exam which was completed elsewhere and a secondary interpretation of the images is requested.

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Quantitative MR Analysis (Preface-4.8)

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- Category III CPT® codes for quantitative analysis of multiparametric-MR (mp-MRI) data with and without an associated diagnostic MRI have been established. Quantitative mp-MRI uses software to analyze tissue physiology of visceral organs and other anatomic structures non-invasively.
- For criteria associated with these types of studies, please see the condition-specific guidelines.

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HCPCS Codes (Preface-4.9)

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- Healthcare Common Procedure Coding System (HCPCS) codes are utilized by some hospitals in favor of the typical Level-III CPT® codes. These codes are typically 4 digits preceded by a C or S.
  - Many of these codes have similar code descriptions to Level-III CPT® codes (i.e., C8931 – MRA with dye, Spinal Canal; and, CPT® 72159 – MRA Spinal Canal).
  - If cases are submitted with HCPCS codes with similar code descriptions to the typical Level-III CPT® codes, those procedures should be managed in the same manner as the typical CPT® codes.
  - HCPCS code management is discussed further in the applicable guideline sections.
- Requests for many Healthcare Common Procedure Coding System (HCPCS) codes, including non-specific codes such as S8042 (Magnetic resonance imaging [MRI], low-field), should be redirected to a more appropriate and specific CPT® code. Exceptions are noted in the applicable guideline sections.

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Whole-Body Imaging (Preface-5)

Guideline

Whole-Body CT Imaging (Preface-5.1)
Whole-Body MR Imaging (Preface-5.2)
PET/MRI (Preface-5.3)
References (Preface-5)

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Whole-Body CT Imaging (Preface-5.1)

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- Whole-body CT or LifeScan (CT Brain, Chest, Abdomen, and Pelvis) for screening of asymptomatic individuals is not a covered benefit. The performance of whole-body screening CT examinations in healthy individuals does not meet any of the current validity criteria for screening studies and there is no clear documentation of benefit versus radiation risk.
- Whole-body low-dose skeletal CT is supported for oncologic staging in Multiple Myeloma. See **Multiple Myeloma and Plasmacytomas (ONC-25)** in the Oncology Imaging Guidelines.

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Whole-Body MR Imaging (Preface-5.2)

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- Whole-body MRI (WBMRI) is, with the exception of select cancer predisposition syndromes and autoimmune conditions discussed below, generally not supported at this time due to lack of standardization in imaging technique and lack of evidence that WBMRI improves outcome for any individual disease state.
  - While WBMRI has the benefit of whole-body imaging and lack of radiation exposure, substantial variation still exists in the number of images, type of sequences (STIR vs. diffusion weighting, for example), and contrast agent(s) used.
- Coding considerations:
  - There are no established CPT® or HCPCS codes for reporting WBMRI.
  - WBMRI is at present only reportable using CPT® 76498. All other methods of reporting whole-body MRI are inappropriate including the following:
    - Separate diagnostic MRI codes for multiple individual body parts
    - MRI Bone Marrow Supply (CPT® 77084)
- Disease-specific considerations:
  - Cancer screening:
    - Interval WBMRI is recommended for cancer screening in individuals with select cancer predisposition syndromes. Otherwise, WBMRI has not been shown to improve outcomes for cancer screening.
      - For additional information, see **Li-Fraumeni Syndrome (LFS) (PEDONC-2.2)**, **Neurofibromatosis 1 and 2 (NF1 and NF2) (PEDONC-2.3)**, **Rhabdoid Tumor Predisposition Syndrome (PEDONC-2.11)**, **Hereditary Paraganglioma-Pheochromocytoma (HPP) Syndromes (PEDONC-2.13)**, **Constitutional Mismatch Repair Deficiency (CMMRD or Turcot Syndrome) (PEDONC-2.15)**, **Infantile Myofibromatosis (PEDONC-2.18)**, or **Bloom Syndrome (PEDONC-2.19)** in the Pediatric and Special Populations Oncology Imaging Guidelines.
  - Cancer staging and restaging:
    - Whole-body MRI has limited indications in staging and restaging of multiple myeloma. See **Multiple Myeloma and Plasmacytomas (ONC-25)** in the Oncology Imaging Guidelines for additional details.
    - Evidence has not been published establishing WBMRI as a standard evaluation for any other type of cancer.
  - Autoimmune disease:
    - WBMRI can be approved in some situations for individuals with chronic recurrent multifocal osteomyelitis.

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- For additional information, see **Chronic Recurrent Multifocal Osteomyelitis (PEDMS-10.2)** in the Pediatric Musculoskeletal Imaging Guidelines.

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PET/MRI (Preface-5.3)

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- PET/MRI is generally not supported for a vast majority of oncologic and neurologic conditions due to lack of standardization in imaging technique and interpretation. However, it is medically necessary in select circumstances when the following criteria are met:
  - The individual meets condition-specific guidelines for PET/MRI OR
  - The individual meets ALL of the following:
    - The individual meets guideline criteria for PET/CT, **AND**
    - PET/CT is not available at the treating institution, **AND**
    - The provider requests PET/MRI in lieu of PET/CT
- When the above criteria are met, PET/MRI is reported using the code combination of PET Whole-Body (CPT® 78813) and MRI Unlisted (CPT® 76498). All other methods of reporting PET/MRI are inappropriate.
  - When clinically appropriate, diagnostic MRI codes can be medically necessary at the same time as the PET/MRI code combination.
- For more information, please see the appropriate condition-based guideline.

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References (Preface-5)

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References (Preface-6.1)

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- Complete reference citations for the journal articles are embedded within the body of the guidelines and/or may be found on the Reference pages at the end of some guideline sections.

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General Guidelines (ONC-1)

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PET Imaging in Oncology (ONC-1.4)
Unlisted Procedure Codes in Oncology (ONC-1.5)
Predisposition Syndromes (ONC-1.6)
References (ONC-1)

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Abbreviations for Oncology Imaging Guidelines

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Abbreviations for Oncology Imaging Guidelines	
ACTH	adrenocorticotropic hormone
AFP	alpha-fetoprotein
ALKP	alkaline phosphatase
AP	anteroposterior
betaHCG	beta human chorionic gonadotropin
CA 125	cancer antigen 125 test
CA 19-9	cancer antigen 19-9
CA 15-3	cancer antigen 15-3
CA 27-29	cancer antigen 27-29
CBC	complete blood count
CEA	carcinoembryonic antigen
CNS	central nervous system
CR	complete response
CTA	computed tomography angiography
DCIS	ductal carcinoma in situ
DLBCL	diffuse large B cell lymphomas
DRE	digital rectal exam
EGD	esophagogastroduodenoscopy
ENT	ear, nose, throat
EOT	end of therapy
ERCP	endoscopic retrograde cholangiopancreatography
ESR	erythrocyte sedimentation rate

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Abbreviations for Oncology Imaging Guidelines	
EUA	exam under anesthesia
EUS	endoscopic ultrasound
FDG	fluorodeoxyglucose
FNA	fine needle aspiration
FUO	fever of unknown origin
GE	gastroesophageal
GI	gastrointestinal
GU	genitourinary
GTR	gross total resection
HG	high-grade
HIV	human immunodeficiency disease
HRPC	hormone refractory prostate cancer
hypermet	hypermetabolic
IFRT	involved field radiation therapy
inv	invasive
LAR	low anterior resection
LCIS	lobular carcinoma in situ
LDH	lactate dehydrogenase
LFT	liver function tests
LND	lymph node dissection
MALT	mucosa associated lymphoid tissue
maint	maintenance
MEN	multiple endocrine neoplasia
MG	myasthenia gravis
MGUS	monoclonal gammopathy of unknown significance
MIBG	I-123 metaiodobenzylguanidine scintigraphy
MRA	magnetic resonance angiography

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Abbreviations for Oncology Imaging Guidelines	
MRCP	magnetic resonance cholangiopancreatography
MRI	magnetic resonance imaging
MUGA	'multiple gated acquisition' cardiac nuclear scan
MWA	microwave ablation
NaF	sodium fluoride
NET	neuroendocrine tumor
NCCN®	National Comprehensive Cancer Network
NHL	non-Hodgkin's lymphoma
NPC	nasopharyngeal carcinoma
NSABP	National Surgical Adjuvant Breast and Bowel Project
NSAIDS	nonsteroidal anti-inflammatory drugs
NSCLC	non-small cell lung cancer
NSGCT	non-seminomatous germ cell tumor
PA	posteroanterior
PCI	prophylactic cranial irradiation
PET	positron emission tomography
COG	Children's Oncology Group
PSA	prostate specific antigen
RFA	radiofrequency ablation
RPLND	retroperitoneal lymph node dissection
SqCCa	squamous cell carcinoma
SCLC	small cell lung cancer
SIADH	syndrome of inappropriate secretion of antidiuretic hormone
TCC	transitional cell carcinoma
TLH	total laparoscopic hysterectomy
TNM	tumor node metastasis staging system
TSH	thyroid-stimulating hormone

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Abbreviations for Oncology Imaging Guidelines	
TURBT	trans-urethral resection of bladder tumor
VIPoma	vasoactive intestinal polypeptide
WLE	wide local incision
WB-MRI	whole body MRI
WM	Waldenstrom's macroglobulinemia
WBXRT	whole brain radiation therapy

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General Guidelines (ONC-1.0)

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- A relevant clinical evaluation or meaningful contact (telephone call, electronic mail or messaging) should be performed prior to considering advanced imaging, unless the individual is undergoing guideline-supported scheduled off therapy surveillance evaluation or cancer screening. The clinical evaluation may include a relevant history and physical examination, including biopsy, appropriate laboratory studies, and results of non-advanced or advanced imaging modalities.
- Unless otherwise stated in the disease-specific guideline, a histological confirmation of malignancy (or recurrence) and the stage of disease is required to perform a medical necessity review of the requested imaging.
- Generally, the studies listed in the disease-specific sections reflect the studies supported by current literature and research for that condition. If a study is not listed, then it is not supported.
- Routine imaging of brain, spine, neck, chest, abdomen, pelvis, bones, or other body areas is not indicated except where explicitly stated in a diagnosis-specific guideline section, or if one of the following applies:
  - Known prior disease involving the requested body area
  - New or worsening symptoms or physical exam findings involving the requested body area (including non-specific findings such as ascites or pleural effusion)
  - New finding on basic imaging study such as plain x-ray or ultrasound
  - New finding on adjacent body area CT/MRI study (i.e., pleural effusion observed on CT Abdomen)
- Unless otherwise stated in the disease-specific guideline, advanced imaging of asymptomatic individuals is not routinely supported without signs or symptoms of systemic involvement of cancer.
- Repeat imaging studies are not generally necessary unless there is evidence of disease progression, recurrence of disease, and/or the repeat imaging will affect an individual's clinical management.
- Conventional imaging performed prior to diagnosis should not be repeated unless there is a delay of at least 6 weeks since previous imaging and treatment initiation or there are new or significantly worsening clinical signs or symptoms

Phases of Oncology Imaging and General Phase-Related Considerations

The following provides general clarity regarding the categories used to describe the phases of imaging throughout these guidelines.

- Screening

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  - Imaging requested for individuals at increased risk for a particular cancer in the absence of known clinical signs or symptoms
- Suspected diagnosis
  - Imaging requested to evaluate a suspicion of cancer, prior to histological confirmation
- Initial work-up and staging
  - Imaging requested after biopsy confirmation and prior to starting specific treatment
- Treatment response or interim restaging
  - Imaging performed during active treatment with chemotherapy, targeted therapy, immunotherapy, radiation therapy, or endocrine therapy. Can be curative or non-curative.
- Restaging of locally treated lesions
  - Imaging performed to evaluate response to primary or metastatic lesion(s) following lesion directed therapy (e.g. cryotherapy, ablation, radioembolization, chemoembolization, radiation therapy).
- Restaging/suspected recurrence
  - Imaging requested when there is suspicion for progression or recurrence of known cancer based on clinical signs or symptoms, laboratory tests, or basic imaging studies.
- Surveillance
  - Imaging performed in individuals who are asymptomatic or have chronic stable symptoms, have no clinical suspicion of change in disease status, and are not receiving active anti-tumor treatment or are receiving maintenance treatment.

The table below provides descriptions of treatment phases, their definitions, and general timeframes.

Treatment Phase	Phase Definition	Imaging Timeframe
After definitive local therapy of primary tumor	Treatment intended to be curative typically using a combination of surgery, radiation therapy, and chemotherapy	Follow surveillance guidelines
During/after neoadjuvant chemotherapy	Treatment given prior to definitive intended curative therapy (usually surgery and/or radiation therapy based), to shrink the cancer to make the definitive curative therapy more effective	Follow initial work-up/staging or restaging/recurrence guidelines

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Treatment Phase	Phase Definition	Imaging Timeframe
During adjuvant chemotherapy	Adjuvant is given after the primary cancer treatment (primary treatment is usually surgery or radiation) with the goal of destroying any remaining cancer cells that cannot be visualized but may still be present, to reduce the risk of recurrence and improve cure/ survival rates beyond initial curative treatments (e.g., colorectal, breast).	Follow surveillance guidelines
After ablative therapy	Minimally invasive medical procedure that destroys abnormal tissue (cancer cells) using heat, cold or other methods, often used as an alternative to surgery or in conjunction with other treatments. Ablative therapy can be considered curative or palliative depending on numerous factors such as other sites of disease, cancer subtype, and ablative technique used.	See disease-specific guidelines

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Treatment Phase	Phase Definition	Imaging Timeframe
Chemotherapy or immunotherapy for active disease	• Measurable disease: Cancerous lesions that can be accurately measured in size to allow for assessment of tumor response. Solid lesions need to be 1 cm of greater while lymph nodes should be 1.5 cm or greater (short axis) • Non-measurable active disease: Lesions that cannot be accurately measured based on size (see above) in addition to lesions such as bone, pleural effusions, ascites, and carcinomatosis. • Active disease: Cancer thought to be "active" whether it is measurable or non-measurable. For lesions that are not clear (i.e., due to small size, chronically stable, not proven to be malignant), provider discretion is to be used to include modality.	Every 2 cycles (generally every 6 to 8 weeks)
During endocrine/ hormonal therapy alone for active disease	E.g., tamoxifen, letrozole, anastrozole, exemestane	Every 3 months (12 weeks)
Active disease on maintenance therapy	Maintenance therapy is given to help keep cancer from coming back after it has shrunk or disappeared following initial therapy and may be given for a finite or indefinite timeframe.	See disease-specific guidelines
Active metastatic disease being monitored off therapy		Every 3 months (12 weeks)

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Treatment Phase	Phase Definition	Imaging Timeframe
Metastatic disease in complete response on or off therapy	Defined as all measurable and non-measurable disease has disappeared (to include normalized tumor markers if applicable) and rarely translates into cure but remission can be sustained for years	• Once complete remission (CR) has been achieved, frequency of imaging should be no sooner than every 3 months and continue for up to 5 years from the time of CR • Follow surveillance guidelines

- Advanced imaging is not indicated for evaluation of in situ or non-invasive cancers or cancer surveillance after complete surgical removal of primary disease unless otherwise stated in the cancer-specific guidelines.
- Advanced imaging is not indicated for monitoring disease in individuals who choose to not receive standard oncologic therapy but may be receiving alternative therapies or palliative care and/or hospice. All advanced imaging indicated for initial staging of the specific cancer type can be approved once when the individual is considering initiation of a standard therapeutic approach (surgery, chemotherapy, or radiation therapy).
- Brain imaging is performed for signs or symptoms of brain disease
  - MRI Brain without and with contrast (CPT® 70553) is the recommended study for evaluation of suspected or known brain metastases. If a non-contrast CT head shows suspicious lesion, MRI Brain may be obtained to further characterize the lesion.
  - CT without and with contrast (CPT® 70470) can be approved when MRI is contraindicated or not available, or if there is skull bone involvement.
  - Certain malignancies including, but not limited to, melanoma and lung cancer have indications for brain imaging for asymptomatic individuals.
  - If stage IV disease is demonstrated elsewhere or if systemic disease progression is noted, refer to disease specific guidelines.
  - Initiation of angiogenesis therapy is not an indication for advanced imaging of the brain in asymptomatic individuals (Avastin/Bevacizumab; <3% risk of bleeding and <1% risk of serious bleeding).
- Bone Scan:

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  - Primarily used for evaluation of bone metastases in individuals with solid malignancies.
  - Indications for bone scan in individuals with history of malignancy include – bone pain, rising tumor markers, elevated alkaline phosphatase or in individuals with primary bone tumor.
  - For evaluation of suspected or known bony metastases, CPT® 78306 (Nuclear bone scan whole body), may be approved.
  - Radiopharmaceutical Localization scan SPECT (CPT® 78803 or CPT® 78831) or SPECT/CT (CPT® 78830 or CPT® 78832) may be approved as an add-on test for further evaluation of a specific area of interest.
  - CPT® codes 78300 (Nuclear bone scan limited), 78305 (Nuclear bone scan multiple areas) or 78315 do not have any indications in oncology nuclear medicine imaging.
- Bone scan supplemented by plain x-rays are the initial imaging modalities for suspected malignant bone pain. For specific imaging indications, see also:
  - **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)**
  - **Bone (Non-Vertebral) Metastases (ONC-31.5)**
  - **Spinal/Vertebral Metastases (ONC-31.6)**
  - **Carcinoma of Unknown Primary Site (ONC-31.7)**
- Advanced imaging used for radiation therapy treatment planning should not be authorized using any of the diagnostic imaging codes for CT, MRI, or PET.
  - Advanced imaging performed in support of radiation therapy treatment planning should be reported with CPT® 76498 for Unlisted MRI or CPT® 76497 for Unlisted CT scan.
- Delay PET/CT for at least 12 weeks after completion of radiation treatment, unless required sooner for imminent surgical resection.
- 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.
- PET/CT may be indicated if:
  - conventional imaging (CT, MRI or bone scan) reveals findings that are inconclusive or negative, with continued suspicion for recurrence
- Unless specified in diagnosis-specific guideline section PET/CT Imaging is NOT medically necessary for:
  - infection, inflammation, trauma, post-operative healing, granulomatous disease, rheumatological conditions
  - concomitant use with separate diagnostic CT studies
  - conclusive evidence of distant or diffuse metastatic disease on recent conventional imaging studies
  - metastatic disease in the central nervous system (CNS)

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- 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 in rare cancers
- surveillance
  - Serial monitoring of individuals who are not currently receiving anti-tumor treatment or are receiving maintenance treatment
  - 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 imaging

- Unless otherwise specified for a specific cancer type, once PET has been documented to be negative for a given individual's cancer or all PET-avid disease has been surgically resected, PET should not be used for continued disease monitoring or surveillance.
- PET/MRI is generally not supported for a vast majority of oncologic conditions due to lack of standardization in imaging technique and interpretation. However, it may be approved select circumstances when the following criteria are met:
  - The individual meets condition-specific guidelines for PET/MRI OR
  - The individual meets ALL of the following:
    - The individual meets guideline criteria for PET/CT, AND
    - PET/CT is not available at the treating institution, AND
    - The provider requests PET/MRI in lieu of PET/CT
  - When the above criteria are met, PET/MRI may be reported using the code combination of PET Whole-Body (CPT® 78813) and MRI Unlisted (CPT® 76498). All other methods of reporting PET/MRI are inappropriate.
    - When clinically appropriate, diagnostic MRI codes may be indicated at the same time as the PET/MRI code combination.
- The specific radiotracer planned to be used with PET/CT imaging is required to perform a medical necessity review. Indications for PET/CT imaging using non-FDG radiotracers are listed in diagnosis-specific guidelines.
  - Supported radiotracers:
    - ^{18}F-FDG
    - ^{68}Gallium DOTATATE (NETSPOT®) for low-grade neuroendocrine tumors and medullary thyroid cancer
    - ^{64}Cu-DOTATATE (DETECTNET®) for low-grade neuroendocrine tumors
    - ^{68}Ga-DOTA-TOC for low-grade neuroendocrine tumors

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        - ^{11}C Choline for prostate cancer
        - ^{18}F-Fluciclovine (AXUMIN®) for prostate cancer
        - ^{68}Ga PSMA-11 for prostate cancer
        - ^{18}F Piflufolastat (Pylarify®) for prostate cancer
        - ^{68}Ga Gozetotide (Illuccix® and Locametz®) for prostate cancer
        - ^{18}F Flotufolastat (Posluma®) for prostate cancer
        - ^{18}F Fluoroestradiol (Cerianna®) for breast cancer
        - ^{18}F Na Fluoride PET bone scan for breast cancer and prostate cancer
    - Unsupported radiotracers:
        - PET/CT imaging using isotopes other than those specified above
- Octreotide scan:
    - Specific for low and intermediate grade neuroendocrine tumors which express specific cell surface somatostatin receptors. See cancer specific guidelines for recommended use.
    - One of the following codes may be approved when Octreotide scan is requested:
    - CPT® 78802 (Radiopharmaceutical localization of tumor whole-body single day study)
    - CPT® 78804 (Radiopharmaceutical localization of tumor whole-body two or more days)
    - In addition to one of the above CPT codes, CPT® 78803 (Radiopharmaceutical localization of tumor SPECT), SPECT CPT® 78831, or hybrid SPECT/CT (CPT® 78830 or 78832) may be approved as an add-on test for further evaluation of a specific area of interest.

Clinical Trials

- Similar to investigational and experimental studies, clinical trial imaging requests will be considered to determine whether they meet these evidence-based guidelines.
- Imaging studies which are inconsistent with established clinical standards, or are requested for data collection and not used in direct clinical management are not supported.

Health Equity Considerations

Health equity is the highest level of health for all individuals; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which individuals are born, grow, live, work, and age. Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include the following: safe housing, transportation, and neighborhoods; racism, discrimination, and violence; education, job opportunities, and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

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Key Principles (ONC-1.1)

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AGE APPROPRIATE GUIDELINES	
Age of Individual	**Appropriate Imaging Guidelines**
≥18 years old at initial diagnosis	• General Oncology Imaging Guidelines, except where directed otherwise by a specific guideline section
<18 years old at initial diagnosis	• Pediatric and Special Populations Oncology Imaging Guidelines, except where directed otherwise by a specific guideline section
15 to 39 years old at initial diagnosis (defined as Adolescent and Young Adult (AYA) oncology individuals)	• When unique guidelines for a specific cancer type exist only in either General Oncology or Pediatric and Special Populations Oncology, AYA individuals should be imaged according to the guideline section for their specific cancer type, regardless of the individual's age • When unique guidelines for a specific cancer type exist in both General Oncology and Pediatric and Special Populations Oncology, AYA individuals should be imaged according to the age rule in the previous bullet

- Conventional Imaging (mostly CT, sometimes MRI or bone scan) of the affected area(s) drives much of initial and re-staging and surveillance. PET is not indicated for surveillance imaging unless specifically stated in the diagnosis-specific guideline sections.
- Brain imaging is performed for signs or symptoms of brain disease.
  - MRI Brain without and with contrast (CPT® 70553) is the recommended study for evaluation of suspected or known brain metastases.
  - MRI Brain without and with contrast (CPT® 70553) may be obtained if a non-contrast CT Head shows suspicious lesion.
  - CT Head without and with contrast (CPT® 70470) can be approved when MRI is contraindicated or not available, or if there is skull bone involvement.
  - Initiation of angiogenesis therapy is not an indication for advanced imaging of the brain in asymptomatic individuals (Avastin/Bevacizumab; <3% risk of bleeding and <1% risk of serious bleeding).

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- Individuals receiving cardiotoxic chemotherapy (such as doxorubicin, trastuzumab, pertuzumab, mitoxantrone, etc.) may undergo cardiac evaluation – at baseline and for monitoring while on active therapy.
  - Echocardiography (CPT® 93306, CPT® 93307, or CPT® 93308) rather than MUGA scan for determination of LVEF and/or wall motion.
    - MUGA Scan may be performed instead of ECHO in individuals who have a low LV ejection fraction of <50% on a prior ECHO or MUGA, pre-existing left ventricular wall motion abnormalities from ischemic or non-ischemic cardiomyopathies, congestive heart failure or when ECHO is technically limited and prevents accurate assessment of LV function.
    - A prior MUGA is not a reason to approve another MUGA (it is not necessary to compare LVEF by the same modality).
  - The timeframe for monitoring the ejection fraction should be determined by the provider, but no more often than baseline and at every 6 weeks.
  - May repeat every 4 weeks if cardiotoxic chemotherapeutic drug is withheld for significant left ventricular cardiac dysfunction.
  - See: **Oncologic Indications for Cancer Therapeutics-Related Cardiac Dysfunction (CTRCD) (CD-12.1)** in the Cardiology Imaging Guidelines
- CTA or MRA of a specific anatomic region is indicated when requested for surgical planning when there is suspected vascular proximity to proposed resection margin.
- Adults (≥18 years) with a diagnosis of Li-Fraumeni Syndrome (LFS) may be screened for malignancy with a Whole-Body MRI (CPT® 76498) on an annual basis. Annual Brain MRI (CPT® 70553) may be performed as part of Whole-Body MRI or as a separate exam. Due to lack of standardization of technique, interpretation, and availability of Whole-Body MRI, individuals with LFS are encouraged to participate in clinical trials.

Use of Contrast

- CT imaging should be performed with contrast for known or suspected body regions, unless contraindicated.
  - Shellfish allergy is not a contraindication to contrast. Individuals with known shellfish allergy do not have contrast reaction any more often than other atopic individuals or individuals with other food allergies.
  - For iodinated contrast dye allergy, either CT scans without contrast or MRI scans without and with contrast are indicated.
  - If CT scanning is considered strongly indicated in an individual with known contrast allergy, CT with contrast may be considered to be safely performed following prednisone premedication over a 24-hour period prior to the study.
- For individuals with renal insufficiency which precludes contrast use, CT without contrast appropriate disease-specific areas should be offered. Further imaging (such as MRI) may be indicated if non-contrast CT results are inconclusive.

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- Severe renal insufficiency, i.e. an eGFR less than 30, is a contraindication for an MRI using a gadolinium-based contrast agent (GBCA) as well. In individuals with eGFR greater than 40, GBCA administration can be safely performed. GBCA administered to individuals with acute kidney injury or severe chronic kidney disease can result in a syndrome of nephrogenic systemic fibrosis (NSF), but GBCAs are not considered nephrotoxic at dosages approved for MRI.
- Gadolinium deposition has been found in individuals with normal renal function following the use of gadolinium based contrast agents (GBCAs).
  - The U.S. Food and Drug Administration (FDA) is investigating the risk of brain deposits following repeated use of GBCAs.
  - The FDA has noted that, “It is unknown whether these gadolinium deposits are harmful or can lead to adverse health effects.” and have recommended:
    - To reduce the potential for gadolinium accumulation, health care professionals should consider limiting GBCA use to clinical circumstances in which the additional information provided by the contrast is necessary.
    - Health care professionals are also urged to reassess the necessity of repetitive GBCA MRIs in established treatment protocols.

Radiation Exposure

- The use of MRI in place of CT scans to reduce risk of secondary malignancy from radiation exposure during CT is not supported by the peer-reviewed literature. Unless otherwise specified in the Guidelines, MRI in place of CT scans for this purpose alone is not indicated. In some instances (i.e., testicular cancer surveillance), MRI may be considered inferior to CT scans.

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Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)

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- This section does not apply to PET imaging. PET imaging considerations can be found in **PET Imaging in Oncology (ONC-1.4)**
- Bone Scan:
  - Primarily used for evaluation of bone metastases in individuals with solid malignancies.
  - Indications for bone scan in individuals with history of malignancy include – bone pain, rising tumor markers, elevated alkaline phosphatase or in individuals with primary bone tumor.
  - For evaluation of suspected or known bony metastases, CPT® 78306 (Nuclear bone scan whole-body), may be approved.
    - Radiopharmaceutical Localization scan SPECT (CPT® 78803 or CPT® 78831) or SPECT/CT (CPT® 78830 or CPT® 78832) may be approved for further evaluation of unclear findings on a whole body scan or clinically suspected lesions with negative whole body bone scan or documented bone metastasis.
  - CPT® codes 78300 (Nuclear bone scan limited), 78305 (Nuclear bone scan multiple areas) or 78315 do not have any indications in oncology nuclear medicine imaging.
- Octreotide scan:
  - Specific for low and intermediate grade neuroendocrine tumors which express specific cell surface somatostatin receptors. See cancer specific guidelines for recommended use.
  - One of the following codes may be approved when Octreotide scan is requested:
    - CPT® 78802 (Radiopharmaceutical localization of tumor whole-body single day study)
    - CPT® 78804 (Radiopharmaceutical localization of tumor whole-body two or more days)
  - In addition to one of the above CPT codes, CPT® 78803 (Radiopharmaceutical localization of tumor SPECT), SPECT CPT® 78831, or hybrid SPECT/CT (CPT® 78830 or 78832) may be approved as an add-on test for further evaluation of a specific area of interest.
- Bone marrow imaging:
  - This study is rarely performed for evaluation of the entire bone marrow in conditions like myeloproliferative disorders, sickle cell bone infarct or ischemia, avascular necrosis or myeloma.

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  - The correct CPT code for this study is CPT® 78104 (Diagnostic Nuclear Medicine Procedures on the Hematopoietic, Reticuloendothelial and Lymphatic System).
- Brain imaging SPECT with Technetium-99m or thallium-201 (CPT® 78803 or CPT® 78830):
  - Immunocompromised individuals with mass lesion detected on CT or MRI for differentiation between lymphoma and infection
  - In distinguishing recurrent brain tumor from radiation necrosis
- Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s):
  - CPT® 78800, CPT® 78801, CPT® 78802, CPT® 78804, CPT® 78803, CPT® 78831 (SPECT), or CPT® 78830 or CPT® 78832 (SPECT/CT)
  - for evaluation of fever of unknown origin and osteomyelitis
  - for suspected infections such as infected central lines, grafts or shunts
- Gallium Isotope Scan:
  - Radiopharmaceutical Localization of tumor (CPT® 78800, CPT® 78801, CPT® 78802, CPT® 78803, or CPT® 78804), SPECT CPT® 78831, or hybrid SPECT/CT CPT® 78830 or 78832
  - This may be rarely used in place of PET/CT scan when PET/CT scan not available and PET/CT is indicated by guidelines for lymphoma, sarcoma, melanoma or myeloma.

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PET Imaging in Oncology (ONC-1.4)

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- CPT codes:
  - PET imaging in oncology should use PET/CT fusion (CPT® 78815 or CPT® 78816) Unbundling PET/CT imaging into separate PET and diagnostic CT codes is otherwise not supported.
  - The decision whether to use skull base to mid-femur (“eyes to thighs”) procedure code for PET (CPT® 78812 or CPT® 78815) or whole-body PET (CPT® 78813 or CPT® 78816) is addressed in the diagnosis-specific guideline sections.
  - ”Limited area” protocol is done infrequently, but may be considered, and is reported with PET (CPT® 78811) or for PET/CT (CPT® 78814).
- Radiotracers:
  - Unless specified otherwise, the term “PET” refers to ^{18}F-FDG-PET and PET/CT fusion studies.
  - Indications for PET/CT imaging using non-FDG radiotracers are listed in diagnosis-specific guidelines. The indications may be as follows:
- Supported radiotracers:
  - ^{18}F-FDG
  - ^{68}Gallium DOTATATE (NETSPOT®) for low-grade neuroendocrine tumors and medullary thyroid cancer
  - ^{64}Cu-DOTATATE (DETECTNET®) for low-grade neuroendocrine tumors
  - ^{68}Ga-DOTA-TOC for low-grade neuroendocrine tumors
  - ^{11}C Choline for prostate cancer
  - ^{18}F-Fluciclovine (AXUMIN®) for prostate cancer
  - ^{68}Ga PSMA-11 for prostate cancer
  - ^{18}F Piflufolastat (Pylarify®) for prostate cancer
  - ^{68}Ga Gozetotide (Illuccix® and Locametz®) for prostate cancer
  - ^{18}F Flotufolastat (Posluma®) for prostate cancer
  - ^{18}F Fluoroestradiol (Cerianna®) for breast cancer
  - ^{18}F Na Fluoride PET bone scan for breast cancer and prostate cancer
- Unsupported radiotracers:
  - PET/CT imaging using isotopes other than those specified above

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CPT/ HCPCS Code	Code Description	Brand or common name	Guideline Section and Cancer Type
A9552	^{18}F Fluoro deoxyglucose	FDG	Various guideline sections where PET is indicated
A9580	^{18}F Sodium fluoride	N/A	ONC-11: Breast Cancer, ONC-19: Prostate Cancer
A9587	^{68}Ga-68 Dotatate	NETSPOT®	ONC-15: Low-grade neuroendocrine tumors, ONC-6: Medullary thyroid cancer
A9515	^{11}C Choline	N/A	ONC-19, Prostate Cancer
A9588	^{18}F-Fluciclovine	AXUMIN®	ONC-19, Prostate Cancer
A9593 A9594	^{68}Ga PSMA-11	N/A	ONC-19, Prostate Cancer
A9595	^{18}F Piflufolastat	Pylarify®	ONC-19, Prostate Cancer
A9596	^{68}Ga Gozetotide	Illuccix®	ONC-19, Prostate Cancer
A9800	^{68}Ga Gozetotide	Locametz®	ONC-19, Prostate Cancer
A9608	^{18}F Flotufolastat	Posluma®	ONC-19, Prostate Cancer
A9591	^{18}F Fluoroestradiol	Cerianna®	ONC-11, Breast Cancer
A9592	^{64}Cu Copper dotatate	Detectnet®	ONC-15, Low-grade neuroendocrine tumors
C9067	^{68}Ga Gallium-DOTA-TOC	N/A	ONC-15, Low-grade neuroendocrine tumors

- Unless specified in diagnosis-specific guideline section PET/CT Imaging is NOT medically necessary for:

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- infection, inflammation, trauma, post-operative healing, granulomatous disease, rheumatological conditions
- concomitant use with separate diagnostic CT studies
- conclusive evidence of distant or diffuse metastatic disease on recent conventional imaging studies
- 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 in rare cancers
- surveillance
  - Serial monitoring of individuals who are not currently receiving anti-tumor treatment or are receiving maintenance treatment
  - 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 imaging
- Unless otherwise specified for a specific cancer type, once PET has been documented to be negative for a given individual's cancer or all PET-avid disease has been surgically resected, PET should not be used for continued disease monitoring or surveillance.

- PET/CT may be indicated if:
  - Conventional imaging (CT, MRI or bone scan) reveals findings that are inconclusive or negative, with continued suspicion for recurrence
  - The individual is undergoing salvage treatment for a recurrent solid tumor with residual measurable disease on conventional imaging and confirmed repeat negative PET imaging will allow the individual to transition from active treatment to surveillance.
  - 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.
- PET/CT for rare malignancies is not covered by these guidelines due to lack of available evidence regarding diagnostic accuracy of PET/CT in the majority of rare cancers. Conventional imaging studies should be used for initial staging and treatment response for these diagnoses. PET/CT can be approved if all of the following apply:

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- Conventional imaging (CT, MRI or bone scan) reveals equivocal or suspicious findings.
- No other specific metabolic imaging (MIBG, octreotide, technetium, etc.) is appropriate for the disease type.
- The submitted clinical information describes a specific decision regarding the individual's care that will be made based on the PET/CT results.

- Delay PET/CT for at least 12 weeks after completion of radiation treatment, unless required sooner for imminent surgical resection.
- PET mammography (PEM, generally reported with CPT® 78811) is considered experimental and investigational at this time.
- PET/MRI is generally not supported for a vast majority of oncologic conditions due to lack of standardization in imaging technique and interpretation. However, it may be approved in select circumstances when the following criteria are met:
  - The individual meets condition-specific guidelines for PET/MRI OR
  - The individual meets ALL of the following:
    - The individual meets guideline criteria for PET/CT, AND
    - PET/CT is not available at the treating institution, AND
    - The provider requests PET/MRI in lieu of PET/CT
  - When the above criteria are met, PET/MRI may be reported using the code combination of PET Whole-Body (CPT® 78813) and MRI Unlisted (CPT® 76498). All other methods of reporting PET/MRI are inappropriate.
    - When clinically appropriate, diagnostic MRI codes may be indicated at the same time as the PET/MRI code combination.

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Unlisted Procedure Codes in Oncology (ONC-1.5)

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- There is often no unique procedure code for a service performed solely for treatment planning purposes. AMA instructions in the CPT state that if no specific code exists for a particular service, the service is reported with an unlisted code.
- Advanced imaging being used for radiation therapy treatment planning should not be authorized using any of the diagnostic imaging codes for CT, MRI or PET. Advanced imaging performed in support of radiation therapy treatment planning should be reported with:
  - **CPT® 76498 for Unlisted MRI** – when MRI will be used for treatment planning of radiation therapy to be delivered ONLY to the brain, prostate and cervix. The use of this code for radiation treatment planning of any other cancers/body parts not listed above may be reviewed on a case-by-case basis.
  - **CPT® 76497 for Unlisted CT** – may NOT be used for radiation treatment planning. CT imaging performed in support of radiation therapy treatment planning is bundled in with the concurrent radiation treatment authorization codes and a separate authorization for treatment planning is not required.
  - Imaging associated with image-directed biopsy should be reported with the corresponding interventional codes. See also: CT-, MR-, or Ultrasound-Guided Procedures (Preface-4.2) in the Preface Imaging Guidelines.
  - For advanced imaging used solely for the purpose of Surgical planning, see: **Unlisted Procedures/Therapy treatment planning (Preface-4.3)** in the Preface Imaging Guidelines

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Predisposition Syndromes (ONC-1.6)

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- For predisposition syndrome screening in adult individuals, see: **Screening Imaging in Cancer Predisposition Syndromes (PEDONC-2)** in the Pediatric and Special Populations Oncology Imaging Guidelines

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References (ONC-1)

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Primary Central Nervous System Tumors (ONC-2)

Guideline

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Primary Central Nervous System Tumors – General Considerations (ONC-2.1)

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- This guideline section applies to primary CNS tumors only. For imaging guidelines in metastatic brain cancer, see the appropriate diagnosis-specific section or **Brain Metastases (ONC-31.3)** for imaging guidelines.
- Primary brain tumors presenting only with uncomplicated headache are very uncommon. Most primary brain tumors present with specific CNS symptoms.
- Histologic confirmation is critical. Therapeutic decisions should not be made on radiographic findings alone, except for ANY of the following:
  - Medically fragile individuals for whom attempted biopsy carries excess medical risk, as stated in writing by both the attending physician and surgeon.
  - Brain stem tumors or other sites where the imaging findings are pathognomonic and the risk of permanent neurological damage is excessive with even a limited biopsy attempt.
- For evaluation of known or suspected spinal cord compromise, see: **Spinal/Vertebral Metastases (ONC-31.6)**
- For suspected brain tumors in neurofibromatosis, see: **Screening Imaging in Cancer Predisposition Syndromes (PEDONC-2)** in the Pediatric and Special Populations Oncology Imaging Guidelines
- Rare tumors occurring more commonly in the pediatric population should be imaged according to the imaging guidelines in: **Pediatric Central Nervous System Tumors (PEDONC-4)** in the Pediatric and Special Populations Oncology Imaging Guidelines.

Indication	Medically Necessary Imaging Study
Characterization and follow up of all brain tumors	• MRI Brain without and with contrast (CPT® 70553) • CT Head without and with contrast (CPT® 70470) when MRI is contraindicated or not available, or there is skull bone involvement • CT Head (contrast as requested) for preoperative planning when requested by the operating surgeon
Preoperative planning or to clarify inconclusive findings on MRI or CT	• MRA Head (CPT® 70544) or CTA Head (CPT® 70496)

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Indication	Medically Necessary Imaging Study
Within 24 to 72 hours following brain tumor surgery	• MRI Brain without and with contrast (CPT® 70553)
Clinical deterioration or development of new neurological features	• MRI Brain without and with contrast (CPT® 70553) • MRI Spine without and with contrast (Cervical-CPT® 72156, Thoracic-CPT® 72157, Lumbar-CPT® 72158) for signs/symptoms of spinal involvement or if spinal involvement is suspected

MR Spectroscopy in Brain Tumors (MRS, CPT® 76390)

- MRS is only medically necessary for use in brain tumors of specified histologies where diagnostic accuracy has been established in peer-reviewed literature.
  - See diagnosis-specific guidelines for MRS indications
- MRS is considered not medically necessary for all other histologies and indications not listed in a diagnosis-specific guideline section.

PET Brain Imaging (CPT® 78608 and CPT® 78609)

- PET Brain Metabolic Imaging (CPT® 78608) is only medically necessary for use in brain tumors of specified histologies where diagnostic accuracy has been established in peer-reviewed literature.
- PET Brain metabolic imaging (CPT® 78608) is considered not medically necessary for all other histologies and indications not listed in a diagnosis-specific guideline section.
- PET Brain perfusion imaging (CPT® 78609) is not medically necessary in the evaluation or management of primary CNS tumors.
- Body PET studies (CPT® 78811, CPT® 78812, and CPT® 78813) and fusion PET/CT studies (CPT® 78814, CPT® 78815, or CPT® 78816) are not medically necessary in the evaluation or management of primary CNS tumors.
- See: **Other Imaging Studies (HD-24)** in the Head Imaging Guidelines for details on other advanced neuro-imaging studies.

Evidence Discussion

Primary central nervous system tumors account for 1.4% of all new cancer diagnoses in the United States and 2.7% of deaths due to cancer. Primary central nervous system tumors develop within any region of the brain. Utilizing the World Health Organization (WHO) classification of tumors, Low grade tumors (WHO I, II) are the most common primary brain tumors. (71.7% of all tumors). High grade tumors (WHO II/IV) account for

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28.3% of all tumors. Meningioma is the most common low grade tumor accounting for 39.7% of all tumors. Glioblastoma is the most common malignant glioma accounting for 15.4% of all tumors. The most recent classification of these tumors is based on histology and on molecular diagnostics.

The primary imaging modality for the evaluation of primary brain tumors is an MRI Brain and Spine (with and without contrast). The standard MRI protocol minimally includes T1 and T2, fluid-attenuated inversion recovery (FLAIR), gradient-echo/susceptibility, diffusion-weighted imaging, and post contrast T1-weighted images to characterize the tumor. MRI provides much better characterization of intracranial parenchymal tumors in comparison to CT. MRI is more sensitive in detecting lesions in the posterior fossa and in evaluation of leptomeningeal spread of tumor. CT imaging (with and/or without contrast) is valuable in the emergent scenario to assist in initial description of the disease. CT imaging of brain and spine should be used in individuals with a contraindication for use of MRI (those with metallic implants or those who experience claustrophobia). If there is bone involvement, CT imaging may be included with MRI for disease assessment.

Advanced imaging modalities may be included to complement standard imaging to further characterize tumors and assist in treatment decisions. MRI perfusion measures blood flow in the tumor and can be useful in differentiating viable tumor versus radiation necrosis, in determining tumor grade and in determining optimal site for biopsy. MR Spectroscopy involves analysis of the levels of certain chemicals in pre-selected voxels (small regions) on an MRI scan done at the same time. MR spectroscopy may be useful in defining grade of tumor or differentiate viable tumor from radiation necrosis. The use of MR spectroscopy is limited to specific histologies based on peer-reviewed literature. A major limitation of both modalities is the added imaging time. Brain FDG-PET imaging may also be considered to differentiate viable tumor versus radiation necrosis, to determine optimal biopsy site and to determine tumor grade. The use of Brain FDG-PET imaging is limited to specific histologies based on peer-reviewed literature.[1,7,8,9,10,11,12]

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Low Grade Gliomas (ONC-2.2)

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- These tumors are defined as having a World Health Organization (WHO) histologic grade of I or II (out of IV), can occur anywhere in the CNS, and includes the following tumors:
  - Pilocytic Astrocytoma
  - Fibrillary (or Diffuse) Astrocytoma
  - Optic Pathway Gliomas
  - Pilomyxoid Astrocytoma
  - Oligodendroglioma
  - Oligoastrocytoma
  - Oligodendrocytoma
  - Subependymal Giant Cell Astrocytoma (SEGA)
  - Ganglioglioma
  - Gangliocytoma
  - Dysembryoplastic infantile astrocytoma (DIA)
  - Dysembryoplastic infantile ganglioglioma (DIG)
  - Dysembryoplastic neuroepithelial tumor (DNT)
  - Tectal plate gliomas
  - Cervicomedullary gliomas
  - Pleomorphic xanthoastrocytoma (PXA)
  - Any other glial tumor with a WHO grade of I or II

Indication	Medically Necessary Imaging Study
Initial Staging	• MRI Brain without and with contrast (CPT® 70553) if not already done • MRI Spine without and with contrast (Cervical-CPT® 72156, Thoracic-CPT® 72157, Lumbar-CPT® 72158) ◦ MRI Spine with contrast only (Cervical-CPT® 72142, Thoracic-CPT® 72147, Lumbar-CPT® 72149) if being performed immediately following a contrast-enhanced MRI Brain

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Indication	Medically Necessary Imaging Study
After initial resection or other treatment (radiation therapy, etc.)	• MRI Brain without and with contrast (CPT® 70553)
For individuals undergoing chemotherapy treatment	• MRI Brain without and with contrast (CPT® 70553) every 2 cycles • Individuals with spinal cord involvement at diagnosis can have MRI without and with contrast of the involved spinal region on the same schedule as MRI brain
ONE of the following: • Determine need for biopsy when transformation to high-grade glioma is suspected based on clinical symptoms or recent MRI findings • Evaluate a brain lesion of indeterminate nature when the study will be used to determine whether biopsy/resection can be safely postponed	ANY of the following: • PET Brain Metabolic Imaging (CPT® 78608) • MRI Perfusion imaging (CPT® 70553)
ONE of the following: • Distinguish low-grade from high-grade gliomas • Evaluate a brain lesion of indeterminate nature when the study will be used to determine whether biopsy/resection can be safely postponed • Distinguish radiation-induced tumor necrosis from progressive disease within 18 months of completing radiotherapy	ANY of the following: • MR Spectroscopy (CPT® 76390) • MRI Perfusion imaging (CPT® 70553)
Suspected intracranial or intraspinal recurrence	• All imaging supported for initial staging

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Indication	Medically Necessary Imaging Study
Surveillance, grade I	• MRI Brain without and with contrast (CPT® 70553) every 3 months for up to 5 years • Individuals with spinal cord involvement at diagnosis: MRI Spine without and with contrast (Cervical-CPT® 72156, Thoracic-CPT® 72157, Lumbar-CPT® 72158) on the same schedule as MRI Brain
Surveillance, grade II (not poor performance status as defined below)	• MRI Brain without and with contrast (CPT® 70553) every 3 months for 5 years, then every 6 months thereafter • Individuals with spinal cord involvement at diagnosis: MRI Spine without and with contrast (Cervical- CPT® 72156, Thoracic- CPT® 72157, Lumbar- CPT® 72158) on the same schedule as MRI Brain
Surveillance, grade II and poor performance status (Karnofsky Performance Score <60)	• MRI Brain without and with contrast (CPT® 70553) every 2 months for 3 years, then every 3 months thereafter • Individuals with spinal cord involvement at diagnosis: MRI Spine without and with contrast (Cervical- CPT® 72156, Thoracic- CPT® 72157, Lumbar- CPT® 72158) on the same schedule as MRI Brain

Evidence Discussion

The primary brain tumors classified as low grade gliomas are listed in the guideline. Initial staging in low grade glioma includes both MRI Brain as well as MRI Whole Spine. Whole spine MRI imaging is indicated for initial staging as the finding of spinal metastases, leptomeningeal disease will impact prognosis, and treatment approaches. MRI studies should be completed both without and with gadolinium contrast. However, MRI Spine with contrast only can be approved if being performed immediately following a contrast-enhanced MRI Brain for patient-centricity to limit time in the MRI machine if requested since the non-contrast component is less essential for the evaluation of spine. MRI imaging is completed after initial resection or radiation to establish a new

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baseline for disease monitoring. If intracranial or intraspinal recurrence is suspected or documented, MRI imaging that was completed for initial staging is repeated.

In individuals undergoing active therapy, MRI imaging may be repeated after every 2 cycles of therapy for disease assessment. If there is spine involvement, MRI Spine of the involved spinal region can be included on this same schedule.

Advanced imaging modalities such as MRI perfusion imaging, MR Spectroscopy and/or PET Brain Metabolic Imaging used in conjunction with standard MRI imaging can be performed to characterize non-invasively changes in the tumor not noted on standard MRI or as problem solving tools with inconclusive findings on MRI imaging. Results of these advanced imaging modalities may be the basis to pursue additional treatment and/or surgical intervention; to define transition of the tumor to a higher grade or to distinguish between radiation-induced radiation necrosis and progressive disease within 18 months of completing radiation therapy.

Surveillance imaging is conducted at a frequency and interval based on published standards noted in the NCCN guidelines. Individuals with poor performance status require more frequent imaging than others because of their higher risk for complications or recurrence.[1] More frequent imaging may be done as clinically indicated by the treating physician, in the event of clinical changes such as development of seizures or neurologic deterioration that are suspicious for disease progression.[8,1,9,7,10,11,12]

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High Grade Gliomas (ONC-2.3)

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- These tumors are defined as having a WHO histologic grade of III or IV (out of IV can occur anywhere in the CNS (though the majority occur in the brain), and include the following tumors:
  - Anaplastic astrocytoma
  - Glioblastoma multiforme
  - Diffuse intrinsic pontine glioma (DIPG, or “brainstem glioma”)
  - Gliomatosis cerebri
  - Gliosarcoma
  - Anaplastic oligodendroglioma
  - Anaplastic ganglioglioma
  - Anaplastic mixed glioma
  - Anaplastic mixed ganglioneuronal tumors
  - Any other glial tumor with a WHO grade of III or IV

Indication	Medically Necessary Imaging Study
Initial Staging	• MRI Brain without and with contrast (CPT® 70553) if not already done • MRI Spine without and with contrast (Cervical-CPT® 72156, Thoracic-CPT® 72157, Lumbar-CPT® 72158) ◦ MRI Spine with contrast only (Cervical-CPT® 72142, Thoracic-CPT® 72147, Lumbar-CPT® 72149) if being performed immediately following a contrast-enhanced MRI Brain
Immediately following partial or complete resection	• MRI Brain without and with contrast (CPT® 70553)
Immediately following radiation therapy (XRT)	• MRI Brain without and with contrast (CPT® 70553) once within 2 to 8 weeks following completion of treatment, and then go to surveillance imaging

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Indication	Medically Necessary Imaging Study
For individuals undergoing chemotherapy treatment	• MRI Brain without and with contrast (CPT® 70553) every 2 cycles • Individuals with spinal cord involvement at diagnosis: MRI without and with contrast of the involved spinal region on the same schedule as MRI Brain
ONE of the following: • Distinguish low-grade from high-grade gliomas • Evaluate a brain lesion of indeterminate nature when the study will be used to determine whether biopsy/resection can be safely postponed • Distinguish radiation-induced tumor necrosis from progressive disease within 18 months of completing radiotherapy	ANY of the following: • MR Spectroscopy (CPT® 76390) • MRI Perfusion imaging (CPT® 70553)
ONE of the following: • Distinguish radiation-induced tumor necrosis from progressive disease • Evaluate inconclusive MRI findings when the study will be used to determine need for biopsy or change in therapy, including a change from active therapy to surveillance • Evaluate a brain lesion of indeterminate nature when the study will be used to determine whether biopsy/resection can be safely postponed	ANY of the following: • MRI Perfusion imaging (CPT® 70553) • PET Brain metabolic imaging (CPT® 78608) ◦ PET Brain is not medically necessary in gliomas occurring in the brain stem due to poor uptake and lack of impact on individual outcomes
Suspected intracranial or intraspinal recurrence	• All imaging supported for initial staging

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Indication	Medically Necessary Imaging Study
Surveillance	• MRI Brain without and with contrast (CPT® 70553) every 2 months for 3 years and every 3 months thereafter • Individuals with spinal cord involvement at diagnosis: MRI Spine without and with contrast (Cervical-CPT® 72156, Thoracic-CPT® 72157, Lumbar-CPT® 72158) on the same schedule as MRI Brain

Evidence Discussion

The primary brain tumors classified as high grade gliomas are listed in the guideline. Initial staging in high grade glioma includes both MRI Brain as well as MRI Whole spine. Whole spine MRI imaging is indicated for initial staging as the finding of spinal metastases and leptomeningeal disease will impact prognosis and treatment approaches. MRI studies should be completed both without and with gadolinium contrast. However, MRI Spine with contrast only can be approved if being performed immediately following a contrast-enhanced MRI Brain for patient-centricity to limit time in the MRI machine if requested, since the non-contrast component is less essential for the evaluation of spine. MRI imaging is indicated after initial resection or radiation to establish a new baseline for disease monitoring. If intracranial or intraspinal recurrence is suspected or documented, MRI imaging that was completed for initial staging is repeated.

In individuals undergoing active therapy, MRI imaging may be repeated after every 2 cycles of therapy for disease assessment. If there is spine involvement, MRI spine of the involved spinal region can be included on this same schedule.

Advanced imaging modalities such as MRI perfusion imaging, MR Spectroscopy and/or PET Brain Metabolic Imaging used in conjunction with standard MRI imaging can be performed as problem solving tools to characterize non-invasively changes in the tumor noted on standard MRI. Results of these advanced imaging modalities may be the basis to pursue additional treatment and/or surgical intervention; to distinguish low-grade from high-grade gliomas; to distinguish between radiation-induced radiation necrosis and progressive disease within 18 months of completing radiation therapy.

Surveillance imaging is conducted at a frequency and interval based on published standards noted in the NCCN guidelines. More frequent imaging may be done as clinically indicated by the treating physician, in the event of a clinical change such as development of seizures or neurologic deterioration that is suspicious for disease progression.[8,1,9,7,10,11,12]

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Medulloblastoma and Supratentorial Primitive Neuroectodermal Tumors (sPNET) (ONC-2.4)

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- Medulloblastoma and sPNET imaging indications in adult individuals are identical to those for pediatric individuals. See: **Medulloblastoma (MDB), Supratentorial Primitive Neuroectodermal Tumors (sPNET), and Pineoblastoma (PEDONC-4.4)** in the Pediatric and Special Populations Oncology Imaging Guidelines.

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Ependymoma (ONC-2.5)

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- Ependymoma imaging indications in adult individuals are identical to those for pediatric individuals. See: **Ependymoma (PEDONC-4.8)** in the Pediatric and Special Populations Oncology Imaging Guidelines.

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Central Nervous System Germ Cell Tumors (ONC-2.6)

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- Central nervous system germ cell tumor imaging indications in adult individuals are identical to those for pediatric individuals. See: **CNS Germinomas and Non-Germinomatous Germ Cell Tumors (NGGCT) (PEDONC-4.7)** in the Pediatric and Special Populations Oncology Imaging Guidelines.

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CNS Lymphoma (Also Known as Microglioma) (ONC-2.7)

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Indication	Medically Necessary Imaging Study
Initial Staging	ALL of the following: • MRI Brain without and with contrast (CPT® 70553) • MRI Cervical Spine without and with contrast (CPT® 72156) • MRI Thoracic Spine without and with contrast (CPT® 72157) • MRI Lumbar Spine without and with contrast (CPT® 72158)
Extra-neural evaluation to confirm CNS primary *Individuals with CNS Lymphoma that is metastatic should be imaged according to: • **Non-Hodgkin Lymphomas (ONC-27)** for individuals age ≥18 years • **Pediatric Aggressive Mature B-Cell Non-Hodgkin Lymphomas (NHL) (PEDONC-5.3)** in the Pediatric Oncology Imaging Guidelines for individuals age ≤17 years	ANY or ALL of the following: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • PET/CT (CPT® 78815) for evaluation of inconclusive findings on CT imaging
Treatment Response	• MRI without and with contrast of all positive disease sites every 2 cycles
Suspected intracranial or intraspinal recurrence	• All imaging supported for initial staging

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Indication	Medically Necessary Imaging Study
Surveillance	• MRI without and with contrast of all positive disease sites every 3 months for 2 years, then every 6 months for 3 years, then annually thereafter

Evidence Discussion

Primary central nervous system lymphoma is an aggressive non-Hodgkin lymphoma that can occur in any location within the intracranial neuraxis (brain, spine, cranial nerves, and leptomeninges). This malignancy can occur in immunocompromised individuals or immunocompetent individuals and represents approximately 4% of all intracranial malignancies. Individuals may present with focal neurological deficits or nonspecific neurological findings depending on the specific location of tumor involvement.

For initial staging, MRI Brain without and with contrast and whole spine imaging without and with gadolinium contrast are indicated. CNS lymphoma has potential to spread throughout the intracranial neuraxis. For confirmation as a primary central nervous system lymphoma, extra neural evaluation is indicated and follows the ONC-27 Non-Hodgkin Lymphoma Guideline. This evaluation includes CT Chest with contrast and CT Abdomen and Pelvis with contrast. FDG PET/CT can be approved if extra-neural CT imaging is inconclusive. Evaluation of treatment response can be assessed after every 2 cycles of treatment with MRI without and with contrast of all positive disease sites. All imaging obtained for initial staging is repeated for suspected disease recurrence to evaluate for metastatic disease. Surveillance imaging includes MRI Brain without and with of all positive disease sites on a schedule outlined in the guideline.[1,12,16]

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Meningiomas (Intracranial and Intraspinal) (ONC-2.8)

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Indication	Medically Necessary Imaging Study
Initial Staging of Intracranial Meningioma	ANY or ALL of the following: • MRI Brain without and with contrast (CPT® 70553) • CT Head (contrast as requested)
Initial staging of Intraspinal Meningioma	ONE of the following: • MRI without and with contrast of appropriate spinal region (Cervical CPT® 72156, Thoracic CPT® 72157, and Lumbar CPT® 72158) OR • CT without and with contrast of the appropriate spinal region (Cervical CPT® 72127, Thoracic CPT® 72130, and Lumbar CPT® 72133)
Inconclusive MRI Brain or CT Head and further imaging is needed to confirm diagnosis	• Dotatate PET/CT Brain (CPT® 78814)
Treatment Response	• MRI without and with contrast of all positive disease sites every 2 cycles
Suspected recurrence of intracranial or intraspinal disease	• All imaging supported for initial staging
Suspected recurrence with inconclusive findings on MRI	Any ONE of the following studies: • Octreotide SPECT Brain (CPT® 78803) • Octreotide SPECT/CT Brain (CPT® 78830) • Dotatate PET/CT Brain (CPT® 78814)

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Indication	Medically Necessary Imaging Study
Surveillance for Grade I (low-grade) and Grade II (atypical) intracranial meningioma (completely resected, partially resected, and unresected)	• MRI Brain without and with contrast (CPT® 70553) every 3 months in year 1, then every 6 months for 5 years ◦ Imaging every 1-3 years thereafter as clinically indicated
Surveillance for Grade I (low-grade) and Grade II (atypical) intraspinal meningioma (completely resected, partially resected, and unresected)	ONE of the following at 3, 6, and 12 months, and then every 6 months for 5 years: • MRI without and with contrast (CPT® 72156 [Cervical spine], CPT® 72157 [Thoracic spine], CPT® 72158 [Lumbar spine]) of the involved spinal level OR • CT without and with contrast (CPT® 72127 [Cervical spine], CPT® 72130 [Thoracic spine], CPT® 72133 [Lumbar spine]) of the involved spinal level • Imaging every 1-3 years thereafter as clinically indicated
Surveillance for Grade III (malignant or anaplastic) Meningioma	• Intracranial Meningioma: MRI Brain without and with contrast (CPT® 70553) every 2 months for 3 years, and then every 3 months thereafter • Intraspinal Meningioma: MRI or CT without and with contrast of the involved spinal region every 2 months for 3 years and then every 3 months thereafter

Evidence Discussion

Meningiomas are the most frequent primary central nervous system tumors, accounting for approximately 34% of all primary brain and spine tumors. Meningiomas are extra-axial, dural-based tumors that are derived from the dura and occur throughout the neuroaxis. Meningiomas are a heterogeneous group of tumors that have been classified in three histologic grades, WHO Grades I (benign), II and III (aggressive). Meningiomas can involve bone resulting in bone overgrowth or infiltration into bony structures. Meningiomas are associated with genetic syndromes and molecular alterations.

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Approaches for classification are evolving to incorporate histopathologic, genetic and molecular characteristics.

The standard imaging modality is MRI without and with contrast. CT imaging is supported, as there is potential for bone involvement. Meningioma overexpresses somatostatin receptors. PET imaging using various radiolabeled somatostatin receptor ligands (SSAs) such as 68Ga-DOTA-Tyr3-octreotide (DOTATOC), 68Ga-DOTA-d-Phe1-Tyr3-octreotide (DOTATATE), or 68Ga-DOTA-l-Nal3-octreotide (DOTANOC) have been used for the diagnostic evaluation of meningioma. PET imaging with these ligands is supported for restaging to clarify inconclusive findings on MRI imaging. ^{111}In-octreotide scintigraphy (octreotide) imaging has a similar imaging indication as ^{68}Ga-DOTATATE PET/CT. In surveillance, the schedule for follow-up MRI/CT imaging is based on tumor grade and extent of residual disease.[1,17,18,19]

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Spinal Cord Tumors (Benign and Malignant) (ONC-2.9)

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- See: **Low Grade Gliomas (ONC-2.2)** and **High Grade Gliomas (ONC-2.3)** for imaging guidelines of low-grade and high-grade gliomas of the spinal cord
- See: **Malignant Tumors of the Spinal Cord (PEDONC-4.9)** in the Pediatric and Special Populations Oncology Imaging Guidelines for other malignant spinal cord tumors
- See: **Neurofibromatosis 1 and 2 (NF1 and NF2) (PEDONC-2.3)** in the Pediatric and Special Populations Oncology Imaging Guidelines for spinal tumors in individuals with Neurofibromatosis 1 or 2
- See: **Spinal/Vertebral Metastases (ONC-31.6)** for known secondary malignancy involving the spine/spinal canal/spinal cord

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Choroid Plexus Tumors (ONC-2.10)

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- Choroid Plexus Tumor imaging indications in adult individuals are identical to those for pediatric individuals. See: **Choroid Plexus Tumors (PEDONC-4.13)** in the Pediatric and Special Populations Oncology Imaging Guidelines.

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Squamous Cell Carcinomas of the Head and Neck (ONC-3)

Guideline

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Squamous Cell Carcinomas of the Head and Neck – General Considerations (ONC-3.0)

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- Individuals with esthesioneuroblastoma should be imaged according to this guideline section.
- Stage III/IV disease encompasses any primary tumor larger than 4 cm or documented lymph node positive disease.

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Squamous Cell Carcinomas of the Head and Neck – Suspected/Diagnosis (ONC-3.1)

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- See: **Neck Masses - Imaging (NECK-5.1)** in the Neck Imaging Guidelines for evaluation of suspected malignancy in the neck.
- PET is medically necessary 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

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Squamous Cell Carcinomas of the Head and Neck – Initial Work-up/Staging (ONC-3.2)

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Indication	Medically Necessary Imaging Study
All Stages of Disease	• CT Neck with contrast (CPT® 70491) **or** MRI Orbits/Face/Neck (OFN) without and with contrast (CPT® 70543) • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250)
For sentinel lymph node evaluation when nodes are not clinically positive	• Lymph system imaging (lymphoscintigraphy, CPT® 78195) ◦ SPECT/CT (CPT® 78830) if requested
Nasal cavity and paranasal sinuses (bony erosion or skull base and intracranial involvement)	ONE of the following: • CT Maxillofacial with contrast (CPT® 70487) • CT Neck with contrast (CPT® 70491) • MRI Orbits/Face/Neck without and with contrast (CPT® 70543)
Nasopharyngeal (NPC) Cancer	• PET/CT (CPT® 78815) • MRI Orbits/Face/Neck without and with contrast (CPT® 70543) is the preferred study ◦ CT Neck (CPT® 70491) **and/or** CT Maxillofacial (CPT® 70487) with contrast if contraindication to MRI • CT Chest with contrast (CPT® 71260)

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Indication	Medically Necessary Imaging Study
For ANY of the following: • Known stage III or IV disease • To determine role for upfront surgery vs chemoradiation in T3-T4 size tumor • Prior to start of primary chemoradiotherapy and have not undergone definitive surgical resection • Inconclusive findings on conventional imaging (CT, MRI) • In order to direct laryngoscopy/exam under anesthesia for biopsy • Pulmonary nodule(s) ≥8 mm in size • Cervical lymph node biopsy positive for squamous cell carcinoma and no primary site identified on CT or MRI Neck and Chest • Inconclusive findings suggestive of disease outside the head and neck area	• PET/CT (CPT® 78815)
Signs or symptoms of abdominal metastatic disease including, but not limited to, elevated liver function tests	• CT Abdomen with contrast (CPT® 74160)
Any head and neck cancer with neurological findings or suspicion of skull base invasion	• MRI Brain without and with contrast (CPT® 70553)

Evidence Discussion

Accurate initial staging guides prognosis and management options. CT Neck with contrast or MRI Neck with and without contrast is required for correct tumor, nodal, and metastases (TNM) staging. A contrasted CT of the chest is also supported if requested.

- Classification of tumor staging involves determination of mass size and extent of invasion, if present, of surrounding structures.
- Size and location (including laterality and nodal basin) of pathologic lymph nodes is also required for accurate nodal staging, which will further direct treatment planning to include the extent of potential neck dissection and/or field of radiation.

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Lymphoscintigraphy is supported, with SPECT if requested, for sentinel node evaluation when nodes are not clinically obviously positive.

- Assessment for potential distant metastases ("M") is based on clinical signs/ symptoms and the presence of advanced locoregional primary disease. Discovery of distant metastasis, or a second primary, shifts management to more systemic options. A heavy smoking history also may be a separate indication for advanced imaging of the chest. Up to 7% to 14% of individuals may have a separate lung primary at the time of initial staging of head and neck SCCa. The use of IV contrast improves the detection of mediastinal and hilar adenopathy, and generally, CT Chest with contrast is preferred. Given the rarity of abdominal or pelvic metastatic disease, abdominopelvic imaging is only supported for signs and symptoms of metastatic disease.
  - Nasopharyngeal carcinoma (NPC) has a relatively high rate of distant metastases compared with other head and neck cancers, being found in 5% to 11% of individuals at the time of initial diagnosis. The most common sites of metastasis are bone (20%), lung (13%), and liver (9%).
- FDG-PET/CT Skull Base to Mid-Thigh detects and localizes primary tumor site, and can be helpful in squamous cell carcinoma (SCCa) of the head and neck with unknown primary. It is also equivalent to and possibly superior to contrast-enhanced CT Neck for accurate diagnosis of regional nodal disease. It is helpful in confirming distant metastases as well. The National Comprehensive Cancer Network (NCCN) recommended FDG-PET/CT for initial staging of any NPC, as well as for individuals with locoregionally advanced SCCa (ie, T3-T4 primary or >/= N1 nodal staging).
  - PET/CT alone, however, is not sufficient for initial staging. It does not provide the necessary anatomic detail of the primary tumor's extent for accurate "T" staging, which is required for best selection of local disease management options. Contrast-enhanced CT Neck or MRI Neck are necessary adjuncts.
  - If imaging fails to reveal an obvious primary, PET/CT should be completed before exam under anesthesia, biopsies, and tonsillectomy, to help identify potential primary sites before any intervention occurs.[1,6,7,8,9,10,11,12]

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Squamous Cell Carcinomas of the Head and Neck – Restaging/Recurrence (ONC-3.3)

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Indication	Medically Necessary Imaging Study
Following complete resection and/or radical neck dissection	See: **Surveillance/Follow-up (ONC-3.4)**
Following primary chemoradiotherapy or radiation therapy in individuals who have not undergone surgical resection of primary tumor or neck dissection	ONE of the following: • CT Neck with contrast (CPT® 70491); **or** • MRI Orbits/Face/Neck without and with contrast (CPT® 70543); **or** • PET/CT (CPT® 78815) no sooner than 12 weeks (3 months) post completion of radiation therapy ◦ If post-treatment PET/CT scan is negative, further surveillance imaging is not routinely indicated.
Post-treatment PET is positive for residual disease	ONE of the following: • CT Neck with contrast (CPT® 70491); **or** • MRI Orbits/Face/Neck without and with contrast (CPT® 70543)
Post-treatment PET is equivocal for residual disease	PET/CT (CPT® 78815) at 3-6 months from prior post-treatment PET/CT
Induction chemotherapy response	• CT Neck with contrast (CPT® 70491) or MRI Orbits/Face/Neck without and with contrast (CPT® 70543) • PET not indicated to assess response to induction chemotherapy
Concern for progression seen on imaging performed at completion of induction chemotherapy	EITHER or ALL of the following: • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) • PET/CT (CPT® 78815)

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Indication	Medically Necessary Imaging Study
Measurable or metastatic disease undergoing active treatment	Every 2 cycles (6-8 weeks): • CT Neck with contrast (CPT® 70491) OR • MRI Orbits/ Face/Neck without and with contrast (CPT® 70543) AND • CT with contrast of involved body sites
Suspected local recurrence	• CT Neck with contrast (CPT® 70491) or MRI Orbits/ Face/Neck without and with contrast (CPT® 70543) • CT Chest with contrast (CPT® 71260)
Biopsy proven local recurrence	ONE of the following: • PET/CT (CPT® 78815) **or** • CT Neck with contrast (CPT® 70491) or MRI Orbits/ Face/Neck without and with contrast (CPT® 70543) and CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250)
Inconclusive conventional imaging (CT or MRI)	• PET/CT (CPT® 78815)
Any of the following: • Known prior thoracic disease • New or worsening pulmonary symptoms • New or worsening chest x-ray findings	• CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250)

Evidence Discussion

Follow-up imaging is required for the evaluation of treatment response. In alignment with the NCCN, a PET/CT is supported following primary chemoradiotherapy in individuals who have not undergone surgical resection of the primary tumor or neck dissection. For individuals receiving induction chemotherapy prior to definitive therapy, a CT or MRI of the primary tumor site to assess response is recommended by NCCN after 2-3 cycles

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of induction, but a repeat PET/CT is not routinely recommended by NCCN unless there are unclear findings on this CT or MRI. For individuals with metastatic disease on active treatment, cross sectional imaging of involved body areas is supported every 2 cycles. PET/CT is supported for only as a problem-solving tool for inconclusive conventional imaging, as the incidence of false positive findings is high in the setting of ongoing inflammation with known disease.

For individuals treated with primary chemoradiotherapy, a negative PET at the 3-6 month timeframe predicts improved survival at 2 years, with a negative predictive value of 95% to 97%. PET/CT performed earlier than this timeframe is associated with higher false-positive findings and should be avoided. CT or MRI neck may be performed **in lieu of** PET/CT, but PET/CT has excellent sensitivity and specificity in this setting, so these studies are generally not supported **in addition to** a PET/CT as they add additional radiation without a clear impact on management.

For suspected local recurrence, CT or MRI of the primary site (neck/face) is supported, as well as CT of the chest as lung and mediastinal nodes are the most common site of metastatic disease at recurrence, often without pulmonary symptoms. PET/CT has a relatively high false-positive rate due to ongoing inflammatory changes, and thus these guidelines do not support PET/CT for suspected recurrence until recurrence is proven by biopsy.[1,6,7,8,9,10,11,12]

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Squamous Cell Carcinomas of the Head and Neck – Surveillance/Follow-up (ONC-3.4)

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Indications	Medically Necessary Imaging Study
Individuals treated with surgical resection of primary site and/or neck dissection (with or without postoperative radiation therapy)	Once within 6 months of completing all treatment: • CT Neck with contrast (CPT® 70491) **or** MRI Orbits/Face/Neck without and with contrast (CPT® 70543) • CT with contrast of any other involved body area
If above post-treatment CT or MRI imaging shows residual abnormalities	ONE of the following, once within 6 months of prior imaging: • CT Neck with contrast (CPT® 70491) OR • MRI Orbits/Face/Neck without and with contrast (CPT® 70543)
Individuals treated with definitive radiation therapy or combined chemoradiation, and post-treatment imaging is negative	Further surveillance imaging is not routinely medically necessary
After initial post-treatment study, for ANY of the following: • Nasopharyngeal primary site • Difficult physical exam due to the effects of treatment (e.g., scarring, etc.) or unable to visualize deep-seated primary site	Annually for 3 years: • CT Neck with contrast (CPT® 70491) **or** MRI Orbits/Face/Neck without and with contrast (CPT® 70543)

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Indications	Medically Necessary Imaging Study
• CT Chest is not medically necessary for surveillance. Individuals with smoking history may undergo annual low dose CT cancer screening if criteria are met (See: **Lung Cancer Screening (CH-33)** in the Chest Imaging Guidelines)	

Evidence Discussion

Timely detection and accurate assessment of the extent of recurrent disease will direct salvage therapy and improve prognosis. A thorough head and neck clinical examination will typically guide any additional imaging that may be necessary, after post-treatment baseline imaging. There is no controlled prospective data showing a survival benefit for long term surveillance imaging. 3-year disease free survival in individuals undergoing surveillance imaging vs those undergoing clinical surveillance only is not significantly different (41% vs 46%, P=0.91). Given the excellent NPV of PET/CT 3-6 months post therapy, and the fact that median time to recurrence is 6 months, eviCore guidelines support cross sectional imaging once within 6 months of completion of therapy, following the initial post treatment PET/CT. For individuals whose primary tumor site cannot be evaluated with physical exam and for patients with nasopharyngeal primary tumors, CT Neck or MRI Face/Orbit/Neck are supported annually for 3 years, as 80% to 90% of recurrences occur within 3 years.

The role of annual CT Chest screening for surveillance of lung metastasis is controversial in head and neck cancer, following primary definitive treatment (surgery, XRT, or systemic therapy/XRT). Further study is needed to determine the extent of the positive effect and/or cost-effectiveness of this approach. Individuals with a heavy smoking history may be at increased risk, and may meet criteria for low-dose CT lung cancer screening as defined in CH-33 in the Chest Imaging Guidelines.[1,6,7,8,9,10,11,12]

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Salivary Gland Cancers (ONC-4)

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Salivary Gland Cancers – General Considerations (ONC-4.0)

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- Salivary gland tumors may originate within the parotid, submandibular, sublingual or minor salivary glands in the mouth.
- Histological subtypes include:
  - mucoepidermoid
  - acinic
  - adenocarcinoma
  - adenoid cystic carcinoma
  - malignant myoepithelial tumors
  - squamous cell carcinoma
  - lymphoma and metastatic squamous carcinoma can occur in the parotid gland
- Over 80% of parotid gland tumors are benign. A bilateral parotid tumor is most likely Warthin's tumor.

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Salivary Gland Cancers – Suspected/ Diagnosis (ONC-4.1)

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- See: **Salivary Gland Disorders (NECK-11)** and **Neck Masses – Imaging (NECK-5.1)** in the Neck Imaging Guidelines for evaluation of salivary gland masses, salivary gland stones, and neck masses.

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Salivary Gland Cancers – Initial Work-up/ Staging (ONC-4.2)

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Indication	Medically Necessary Imaging Study
Biopsy-proven malignancy	ONE of the following: • MRI Orbits/Face/Neck without and with contrast (CPT® 70543) • CT Neck with contrast (CPT® 70491) • CT Neck without contrast (CPT® 70490)
Skull base invasion	• MRI Brain without and with contrast (CPT® 70553)
• Adenoid cystic carcinoma • Lymphadenopathy in the neck • Pulmonary signs or symptoms • Abnormal chest x-ray	• CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250)
Inconclusive findings on conventional imaging	• PET/CT (CPT® 78815)

Evidence Discussion

There are over 40 histologies of salivary gland malignancies, with different patterns of presentation and invasiveness. The choice of MRI vs CT depends on location of tumor, specific symptoms, and individual characteristics. CT may be useful to assess stones and sialadenitis, which may mimic tumor, and is superior for assessing cortical bone erosion. MRI is superior in the assessment of extent of soft tissue disease and perineural invasion. Contrast is recommended in all studies to better outline primary site and to better assess nodal involvement.

In individuals who present with metastatic disease outside the neck, 90% are lung/ chest node metastases. Metastatic disease to lung is most common with adenoid cystic carcinoma and chest imaging is supported in all individuals with this histology. Contrast should be used to allow for assessment of nodal disease in the chest. In other histologies, metastatic disease is less common, and thus chest imaging is only supported in individuals with neck adenopathy, abnormal chest x-ray, or pulmonary signs and symptoms.

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Perineural and skull base invasion may occur with salivary gland cancers, particularly with adenoid cystic carcinoma, where perineural spread is seen in 50% to 60% of individuals. When skull base invasion is clinically suspected an MRI Brain with and without contrast is supported by these guidelines in the interest of patient safety. MRI with and without gadolinium and with fat-saturated, T1 weighted MRI sequences is the most sensitive technique to evaluate for invasion of skull base and perineural invasion.

The role of PET/CT remains controversial in salivary gland cancers. Several studies show no statistically significant different in outcomes with imaging with PET/CT vs conventional imaging. The rate of change in treatment plan based on imaging with PET/CT is widely variable across studies, ranging from 15% to 47%. PET/CT is not adequate to distinguish benign from malignant parotid tumors. Benign tumors such as Warthin's tumor can have FDG uptake, and low-grade malignant tumors may not take up FDG. Healthy salivary glands may also exhibit FDG uptake and obscure tumors. While there is emerging evidence in the use of FDG-PET/CT and PET/MRI to assess for distant disease and perineural spread, it is not considered routine at this time and is not routinely recommended by the NCCN. PET/CT thus remains reserved as a problem-solving tool when conventional imaging is inconclusive.[1-13]

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Salivary Gland Cancers – Restaging/ Recurrence (ONC-4.3)

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Indication	Medically Necessary Imaging Study
After complete surgical resection	One-time imaging to establish baseline within 3-4 months of surgical resection is medically necessary using ONE of the following: • MRI Orbits/Face/Neck without and with contrast (CPT® 70543) • CT Neck with contrast (CPT® 70491) • CT Neck without contrast (CPT® 70490)
Individuals with unresected disease receiving systemic therapy (chemotherapy)	Every 2 cycles: • CT Neck with contrast (CPT® 70491) OR MRI Orbits/Face/Neck without and with contrast (CPT® 70543) • CT with contrast or MRI without and with for any other sites of disease
Recurrence or progression suspected based on new or worsening signs or symptoms	ONE of the following: • CT Neck with contrast (CPT® 70491) • MRI Orbits/Face/Neck without and with contrast (CPT® 70543) In addition, for all individuals: • CT Chest with contrast (CPT® 71260)
Inconclusive findings on conventional imaging	• PET/CT (CPT® 78815)
All other individuals	• No routine advanced imaging

Evidence Discussion

NCCN supported one-time imaging with CT or MRI to establish a new baseline for future comparison.[1] CT or MRI based on initial tumor and individual characteristics

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is supported every 2 cycles of systemic chemotherapy. If recurrence of progression is clinically suspected at any time, CT neck with contrast or MRI without and with contrast is supported based on prior tumor characteristics and symptoms, per NCCN recommendations and American College of Radiology ACR Appropriateness Criteria®. The incidence of metastatic disease to the chest is higher at recurrence than at initial presentation, with 63% of individuals with metastatic recurrence presenting with metastatic disease to the chest, so CT Chest is supported for suspected recurrence. Contrast should be used to allow better assessment of nodal disease, in addition to parenchymal lesions. PET/CT remains a tool for the clarification of inconclusive findings on conventional imaging. Any CNS symptoms warrant MRI with further guidance in guideline ONC-31.3.[1-13]

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Salivary Gland Cancers – Surveillance/ Follow-up (ONC-4.4)

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Indication	Medically Necessary Imaging Study
Total surgical resection	• No routine advanced imaging
Unresectable or partially resected disease, including those treated with radiation therapy	• Either CT Neck with contrast (CPT® 70491) or MRI Orbits/Face/Neck without and with contrast (CPT® 70543) once within 6 months of completion of treatment
Adenoid cystic carcinoma	ANY of the following, annually for up to 10 years: • CT Neck with contrast (CPT® 70491) or MRI Orbits/Face/Neck without and with contrast (CPT® 70543) • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250)

Evidence Discussion

The mainstay of surveillance for head and neck cancers including salivary gland carcinoma are frequent history and physical examination. For most histologies, no survival benefit has been documented with imaging surveillance over clinical surveillance. The NCCN notes most recurrences are picked up by patient report of symptoms. For all histologies other than adenoid cystic carcinoma, guidelines support imaging of the primary tumor site once within 6 months from completion of therapy to establish post-treatment baseline, with further imaging guided by signs and symptoms of recurrence. Adenoid cystic carcinoma has the highest incidence of metastatic disease, with over 60 percent of individuals presenting with metastatic disease at recurrence having a history of this histology. They also have the longest risk of recurrence, with a median time to recurrence of 3 years with some recurrences occurring as late as 10 years from diagnosis. For individuals with a history of adenoid cystic carcinoma, CT Neck with contrast or MRI Orbit/Face/Neck as well as CT Chest with or without contrast are supported annually for up to 10 years.[1-13]

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Melanomas and Other Skin Cancers (ONC-5)

Guideline

Melanoma – General Considerations (ONC-5.0)
Melanoma – Suspected/Diagnosis (ONC-5.1)
Melanoma – Initial Work-up/Staging (ONC-5.2)
Melanoma – Restaging/Recurrence (ONC-5.3)
Melanoma – Surveillance/Follow-up (ONC-5.4)
Non-Melanoma Skin Cancers – General Considerations (ONC-5.5)
Non-Melanoma Skin Cancers – Initial Work-up/Staging (ONC-5.6)
Non-Melanoma Skin Cancers – Restaging/Recurrence (ONC-5.7)
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Ocular Melanoma (ONC-5.9)
References (ONC-5)

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Melanoma – General Considerations (ONC-5.0)

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- Melanomas can metastasize in an unpredictable fashion.

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Melanoma – Suspected/Diagnosis (ONC-5.1)

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Indication	Medically Necessary Imaging Study
All	• Imaging is not medically necessary until histologic diagnosis is confirmed

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Melanoma – Initial Work-up/Staging (ONC-5.2)

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Indication	Medically Necessary Imaging Study
Stage 0 or IA (in situ or disease <1 mm)	• Routine advanced imaging is not medically necessary
• Stage IB (<0.8 mm with ulceration or 0.8-1 mm without or with ulceration) • Stage II (lesions >1 mm thick, but node negative)	• CT with contrast or MRI without and with contrast of specific areas, only if signs or symptoms indicate need for further evaluation
For sentinel lymph node evaluation in stages IB and II	• Lymph system imaging (lymphoscintigraphy, CPT® 78195) ◦ SPECT/CT (CPT® 78830) if requested
Any of the following: • Stage III (sentinel node positive, palpable regional nodes) • Stage IV (metastatic)	• MRI Brain without and with contrast (CPT® 70553) AND one of the following: • PET/CT (CPT® 78815 or CPT® 78816) OR • CT Chest with contrast (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177)
• Head or neck primary site • Palpable lymphadenopathy in the neck • Mucosal melanoma of the head or neck region	In addition to above initial staging imaging, if PET/CT not performed: • CT Neck with contrast (CPT® 70491)
• Primary site of melanoma is unknown **and** CT Chest, Abdomen, and Pelvis are negative	• PET/CT (CPT® 78815 or CPT® 78816)

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Evidence Discussion

Formal diagnosis and clinical staging of melanoma needs to take place before any imaging is completed as 84% of individuals present with localized disease, 9% with regional disease, and 4% with distant metastatic disease. Stage 0 (in situ) or 1A does not require routine advanced imaging as the 5 year survival rate is >98% with very little risk for recurrence or metastases. For Stage IB or II disease, sentinel lymph node mapping is indicated and depending on results, survival rates range from 50% to 90% that also incorporates tumor thickness, ulceration and mitotic rate. The yield of imaging in screening individuals with clinical Stage 0-II disease for asymptomatic distant metastatic disease is very low due to low sensitivity and false positive findings. Therefore, the NCCN does not recommend imaging unless needed for surgical planning or to evaluate specific signs or symptoms of disease. Stage III or IV disease can be staged using PET/CT or CT Chest/Abdomen/Pelvis, with PET/CT often preferred due to its superiority over CT in detecting distant metastases. Baseline MRI brain is indicated with or without symptoms due to high risk of CNS involvement estimated to be 15.8% at 5 years for Stage III and up to 60% overall in individuals with advanced stage disease. If primary site of melanoma is unknown and CT Chest/Abdomen/Pelvis negative, PET/CT can be performed due to its higher sensitivity and ability to image the extremities.[1,7,17-19]

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Melanoma – Restaging/Recurrence (ONC-5.3)

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- All recurrences should be confirmed histologically, except when excessive morbidity from a biopsy may occur, such as a biopsy requiring craniotomy.

Indication	Medically Necessary Imaging Study
Individuals receiving chemotherapy, with measurable disease, every 2 cycles (commonly every 6 to 8 weeks)	• CT Chest with contrast (CPT® 71260); **and** CT Abdomen and Pelvis with contrast (CPT® 74177)
All in situ recurrences	• Restaging imaging is not medically necessary after adequate aggressive local therapy (See Surveillance below)
Documented or clinically suspected (see top of page regarding biopsy morbidity) recurrence at: • True scar recurrence (if re-excision suggests more than in situ disease) • In-transit disease • Regional lymph nodes • Metastatic site	• CT Chest with contrast (CPT® 71260); **and** CT Abdomen and Pelvis with contrast (CPT® 74177) In addition, for all individuals: • MRI Brain without and with contrast (CPT® 70553) In addition, for head or neck primary: • CT Neck with contrast (CPT® 70491)
ANY of the following: • Inconclusive findings on conventional imaging • Isolated metastatic site found on conventional imaging	• PET/CT (CPT® 78815 or CPT® 78816)

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Indication	Medically Necessary Imaging Study
Brain imaging is indicated for: • New discovery of metastatic disease or progression of metastatic disease • Signs or symptoms of CNS disease • If considering Interleukin (IL-2) therapy	• MRI Brain without and with contrast (CPT® 70553)

Evidence Discussion

Individuals receiving chemotherapy with measurable disease can undergo CT Chest/Abdomen/Pelvis every 2 cycles. In situ recurrences do not require restaging imaging due to its high cure rate while recurrence at the primary site, in-transit disease, regional nodes and metastatic site can undergo CT Chest/Abdomen/Pelvis and MRI Brain due to the higher risk of CNS involvement. PET/CT is reserved for inconclusive findings or isolated metastatic site found on CT imaging to guide decisions on local versus systemic therapy. MRI Brain is also indicated for newly diagnosed or progressive metastatic disease, signs or symptoms of CNS involvement or if IL-2 therapy is being considered.[1]

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Melanoma – Surveillance/Follow-up (ONC-5.4)

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Indication	Medically Necessary Imaging Study
Stage 0, IA, IB and IIA Melanomas	• No routine advanced imaging
Stage IIB, IIC, IIIA and IIIB Melanomas	• CT Chest (CPT® 71260) **and** CT Abdomen and Pelvis (CPT® 74177) with contrast every 6 months for 2 years, then annually for 3 years • For melanoma arising from extremities, advanced imaging of the primary site is not routinely medically necessary for surveillance in asymptomatic individuals.
Stage IIIC and IV Melanomas	• CT Chest (CPT® 71260) **and** CT Abdomen and Pelvis (CPT® 74177) with contrast every 3 months for 2 years, then every 6 months for 3 years • MRI Brain without and with contrast (CPT® 70553) annually for 3 years • For melanoma arising from extremities, advanced imaging of the primary site is not routinely medically necessary for surveillance in asymptomatic individuals.
Mucosal Melanoma of the head or neck region	In addition to above stage-based surveillance imaging, ONCE within 6 months of completing all treatment: • CT Neck with contrast (CPT® 70491) or MRI Orbits/Face/Neck without and with contrast (CPT® 70543) • CT with contrast of any other involved body area
Liver metastases treated with focal therapy	• See: **Liver Metastases (ONC-31.2)**

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Evidence Discussion

The majority of recurrences, especially in those with early stage disease, are detected clinically by either the patient or during physical exam thus supporting no surveillance imaging in stage 0, 1A, 1B and IIA disease. Furthermore, additional studies have reported low yield, significant false positivity (often associated with increased anxiety and medical costs), and risks of cumulative radiation exposure. Individuals with more advanced disease are more likely to recur, and recur more quickly, with the risk of recurrence reaching low levels after only 2.7 years, thereby supporting stage IIB/IIC as well as stage IIIA/IIIB undergoing CT Chest/Abdomen/Pelvis every 6 months for 2 years then annually for 3 years. Due to the even high risk of early distant recurrence, Stage IIIC/IV should undergo CT Chest/Abdomen/Pelvis every 3 months for 2 years then every 6 months for 3 years as well as MRI brain annually for 3 years. The utility of PET/CT scan in sentinel lymph positive stage III melanoma was minimal with only 2 out of 38 patients (108 total scans) being true positive with 9 scans showing false positive results thus supporting CT rather than PET/CT imaging in this setting. For melanoma arising from extremities, advanced imaging of the primary site is not indicated in asymptomatic individuals. Mucosal melanoma of the head or neck region can also undergo on a one-time basis CT Neck or MRI Orbits/Face/Neck or CT of any other involved body area within 6 months of completing treatment.

The NCCN did not specify the type of imaging required during the workup, response assessment, or surveillance other than listing "cross-sectional with or without brain imaging" thus allowing the provider to determine if CT or PET/CT may be most appropriate. Among the many factors playing a role in this decision are cost, convenience, false positives/false negatives, dye, and radiation exposure.[1,21,22]

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Non-Melanoma Skin Cancers – General Considerations (ONC-5.5)

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- Advanced imaging is generally not medically necessary for basal cell and squamous cell skin cancers.
- PET/CT scan is not medically necessary for evaluation of non-melanoma skin cancers unless specified within the guidelines below (e.g., Merkel cell carcinoma).
- Merkel cell carcinoma is an unusual skin cancer with neuroendocrine-like histologic features, which has a high propensity (25% to 33%) for regional lymph node spread and occasionally, metastatic spread to lungs.
- Merkel cell carcinoma may present as a primary cancer or as a skin metastasis from a non-cutaneous primary neuroendocrine carcinoma (i.e., small cell lung cancer), therefore conventional imaging is indicated initially to confirm the absence of metastasis prior to considering PET scan.

Evidence Discussion

Advanced imaging to include PET/CT is generally not indicated for basal cell (BCC) or squamous cell (SCC) skin cancers. The incidence of metastatic BCC was found to be <1% at 14 years of follow-up while metastatic SCC is noted to be rare. Merkel cell carcinoma, due to its high propensity (25% to 33%) for regional lymph node spread as well as distant metastases (12% to 20%), conventional imaging is indicated initially prior to considering PET scan.[3,15,16]

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Non-Melanoma Skin Cancers – Initial Work-up/Staging (ONC-5.6)

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Indication	Medically Necessary Imaging Study
Body area with unexplained signs or symptoms	• CT with contrast of that body area
Perineural invasion or local regional extension (i.e. bone; deep soft tissue) involvement	ONE of the following of the primary site: • MRI without contrast **or** without and with contrast • CT (contrast as requested)
Skin lesion may be a dermal metastasis from distant primary	• CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast • PET/CT (CPT® 78815 or CPT® 78816) if conventional imaging (CT or MRI) is unable to identify a primary site
Squamous cell carcinoma head or neck skin with regional lymphadenopathy	• CT Neck (CPT® 70491) and CT Chest (CPT® 71260) with contrast
Merkel Cell carcinoma	• CT Chest with contrast (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of other involved body area(s) • PET/CT (CPT® 78815 or CPT® 78816) if inconclusive conventional imaging • Lymph system imaging (lymphoscintigraphy, CPT® 78195) for sentinel lymph node evaluation ◦ SPECT/CT (CPT® 78830) if requested
Signs or symptoms of CNS involvement	• MRI Brain with and without contrast (CPT® 70553)

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Evidence Discussion

A body area with unexplained signs or symptoms can undergo imaging with CT with contrast. For SCC, MRI or CT of the primary site with MRI favored if there is perineural or deep soft tissue involvement while CT is preferred for bone disease. If the skin lesion is felt to be a dermal metastasis from a distant primary, CT Chest/Abdomen/Pelvis with contrast is the initial recommended imaging with PET/CT indicated if conventional imaging is unable to identify a primary site and especially if the primary tumor may involve an extremity.[3-5]

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Non-Melanoma Skin Cancers – Restaging/Recurrence (ONC-5.7)

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- All recurrences should be confirmed histologically, except when excessive morbidity from a biopsy may occur, such as a biopsy requiring craniotomy.

Indication	Medically Necessary Imaging Study
Recurrence where planned therapy is more extensive than simple wide local excision	• CT with contrast of the primary and recurrent site(s)
Suspected or biopsy-proven recurrence of Merkel cell carcinoma	• CT Chest (CPT® 71260) **and** CT Abdomen and Pelvis (CPT® 74177) with contrast • CT with contrast of other symptomatic body area(s)
Inconclusive findings on conventional imaging	• PET/CT (CPT® 78815 or 78816)
Signs or symptoms of CNS involvement	• MRI Brain without and with contrast (CPT® 70553)

Evidence Discussion

For recurrences where planned therapy is more extensive than simple wide local excision, CT with contrast of primary site and recurrent site(s) is indicated. Merkel cell carcinoma recurrence can be evaluated with CT Chest/Abdomen/Pelvis plus any other symptomatic areas. PET/CT can be done for inconclusive findings on conventional imaging. MRI Brain indicated for signs or symptoms of CNS involvement.[3-5]

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Non-Melanoma Skin Cancers – Surveillance/Follow-up (ONC-5.8)

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Indication	Medically Necessary Imaging Study
Merkel cell cancer with any of the following high-risk factors: • Stage II-IV • Male individuals • Immunosuppression • Merkel Cell polyomavirus negative status • Age ≥70 • Non-sentinel lymph node metastases	• CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast every 6 months for 5 years • Add CT Neck with contrast (CPT® 70491) if known prior neck disease or scalp/facial/neck disease
All others	• Routine advanced imaging for surveillance is not medically necessary • Imaging only for signs and symptoms of recurrent disease

Evidence Discussion

In node positive Merkel cell carcinoma, recurrence rates have been found to be up to 33% at 5 years. In addition, males are twice as likely to develop Merkel Cell carcinoma. Also, the likelihood of developing Merkel Cell increases with age. One study showed that 73.6% of Merkel Cell cases are diagnosed at age greater than 70.[24] Additional risk factors for recurrence of Merkel Cell are polyomavirus negative status, non-sentinel lymph node metastases, and immunosuppression. Routine imaging is not indicated for SCC or BCC in the absence of signs and symptoms of recurrence.[3-5]

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Ocular Melanoma (ONC-5.9)

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General Considerations

- Approximately 95% of ocular melanomas arise from the uvea (iris, ciliary body and choroid) and 5% arise from the conjunctiva or orbit.
- Biopsy is usually not necessary for initial diagnosis of uveal melanoma but may be useful in cases when diagnosis is uncertain (e.g., amelanotic tumors, retinal detachment) or for prognostic analysis and risk stratification.
- Treatment is directed to the affected eye with systemic therapy reserved only for known metastatic disease.
- The most common site of metastatic disease is the liver.
- Surveillance of the affected eye is with clinical examination only; advanced imaging is supported for surveillance of systemic metastatic disease based on individual risk factors. See risk categories below for surveillance recommendations.

Ocular Melanoma Risk Categories

Low Risk	Medium Risk	High-Risk
T1	T2 and T3	T4
Class IA	Class IB	Class 2
Spindle cell histology	Mixed Spindle and Epitheloid cells	Epitheloid cell histology
No extraoccular extension	No extraoccular extension	Extraoccular extension present
No ciliary body involvement	No ciliary body involvement	Ciliary body involvement present
Chromosome mutations: • Disomy 3 • EIF1AX mutation • Gain of chromosome 6p	Chromosome mutations: • SF3B1 mutation	Chromosome mutations: • BAP1 mutation • PRAME mutation • Monosomy 3 • Gain of chromosome 8q

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Indication	Medically Necessary Imaging Study
Initial staging of suspected or biopsy-proven uveal melanoma	ANY or ALL of the following: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177), OR MRI Abdomen without and with contrast (CPT® 74183) with CT Pelvis with contrast (CPT® 72913), OR MRI Abdomen without and with contrast (CPT® 74183) with MRI Pelvis without and with contrast (CPT® 72197) • MRI Orbits/Face/Neck without and with contrast (CPT® 70543)
Neurological signs/ symptoms	• MRI Brain without and with contrast (CPT® 70553)
Restaging/Suspected Recurrence	ANY or ALL of the following: • MRI Brain without and with contrast (CPT® 70553) • MRI Orbits/Face/Neck without and with contrast (CPT® 70543) • CT Chest with contrast (CPT® 71260) AND one of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) OR • MRI Abdomen without and with contrast (CPT® 74183) with CT Pelvis with contrast (CPT® 72913) OR ◦ Ultrasound Abdomen substituted for MRI Abdomen if requested • MRI Abdomen without and with contrast (CPT® 74183) with MRI Pelvis without and with contrast (CPT® 72197)
Surveillance for Low Risk disease	Annually for 10 years: • CT Chest with contrast (CPT® 71260) • CT Abdomen with contrast (CPT® 74160) or MRI Abdomen without and with contrast (CPT® 74183)
Surveillance for Medium Risk disease	Every 6 months up to year 10: • CT Chest with contrast (CPT® 71260) • CT Abdomen with contrast (CPT® 74160) or MRI Abdomen without and with contrast (CPT® 74183)

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Indication	Medically Necessary Imaging Study
Surveillance for High-risk disease	Every 3 months for 5 years, then every 6 months up to year 10: • CT Chest with contrast (CPT® 71260) • CT Abdomen with contrast (CPT® 74160) or MRI Abdomen without and with contrast (CPT® 74183)

Evidence Discussion

Approximately 95% of ocular melanoma occur in the uvea and 5% from the conjunctiva or orbit. Biopsy may not be mandatory for diagnosis but should be performed if diagnosis is uncertain or for prognostic analysis and risk stratification. Less than 3% of cases present with metastatic disease with 5 year risk of metastasis ranging from 3% to 5% in Stage I to 44% or higher in Stage III. The most common site of metastatic disease is the liver (80%) but may also spread to the lungs, bone, skin/soft tissue and lymph nodes. Surveillance of the affected eye is with clinical examination only with advanced imaging supported based on individual risk factors. Initial staging includes MRI orbits/face/neck to determine extraocular extension that impacts treatment planning (radiation therapy versus enucleation). While the risk of baseline metastases may be low, the NCCN favors baseline staging before treatment to include CT Chest/Abdomen/Pelvis in addition to aforementioned MRI. MRI Brain is indicated with any neurologic signs or symptoms. Restaging/recurrence with same imaging as initial staging as well as including MRI Brain. Surveillance: Local recurrence is rare (<10%) and the development of metastatic disease is much more common (up to 70% up to 20 years after initial diagnosis) hence the following recommendations for surveillance that does not include local imaging unless clinically indicated. For low risk disease, CT Chest with CT or MRI of the abdomen annually for 10 years. For medium risk disease, same as low risk but every 6 months for a total of 10 years. For high-risk disease, every 3 months for 5 years, then annually for a total of 10 years. The NCCN recognized the optimal surveillance strategy is an issue of debate due to overall low yield of testing and the risk of cumulative radiation exposure.[2, 25]

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Thyroid Cancer (ONC-6)

Guideline

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Thyroid Cancer – General Considerations (ONC-6.0)

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- Individuals of all ages with thyroid cancer are imaged according to this guideline.
- Whole-Body Thyroid Nuclear scan (also known as whole-body radioiodine scan) is coded with CPT® 78018. If CPT® 78018 is obtained and found to be positive, CPT® 78020 is medically necessary as an add-on test to evaluate the degree of iodine uptake.
- Single photon emission computed tomography (SPECT) imaging – Radiopharmaceutical Localization of Tumor SPECT (CPT® 78803 or CPT® 78831) or SPECT/CT Hybrid study (CPT® 78830 or CPT® 78832) may complement planar and pinhole imaging and can be approved as an add-on wherever radioiodine (RAI) scans are indicated.
- Whole-Body Thyroid Nuclear scan (also known as whole-body RAI scan) is the imaging modality of choice for differentiated thyroid cancers, as these are usually not well visualized on FDG-PET/CT scans. Individuals who have RAI-diagnostic scan negative and PET-positive disease will generally not respond to RAI treatment, whereas individuals who have PET-negative and RAI-diagnostic scan negative disease may still be candidates for empiric RAI treatment.
- Radioiodine (RAI) refractory disease is defined as: (i) the malignant/metastatic tissue does not ever concentrate RAI (no uptake outside the thyroid bed at the first therapeutic WBS), (ii)the tumor tissue loses the ability to concentrate RAI after previous evidence of RAI-avid disease (in the absence of stable iodine contamination), (iii) RAI is concentrated in some lesions but not in others, and (iv) metastatic disease progresses despite significant concentration of RAI.

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Thyroid Cancer – Suspected/Diagnosis (ONC-6.1)

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- See: **Thyroid Nodule (NECK-8.1)** in the Neck Imaging Guidelines for suspected thyroid malignancies.

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Thyroid Cancer – Initial Work-up/Staging (ONC-6.2)

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Follicular, Papillary, and Hürthle Cell (Oncocytic) Carcinomas	Medically Necessary Imaging Study
ONE of the following: • Locally advanced disease or fixation suggested by clinical exam and/or ultrasound • Substernal or bulky disease • Disease precluding full ultrasound examination • Vocal cord paresis	ONE of the following: • MRI Neck without contrast (CPT® 70540) • MRI Neck without and with contrast (CPT® 70543) • CT Neck with contrast (CPT® 70491) if contrast study is necessary for complete pre-operative assessment and use of IV contrast will not delay post-operative use of RAI therapy.
• Extent of thyroid remnant cannot be accurately ascertained from the surgical report, neck ultrasound, or cross-sectional imaging • Unresectable residual disease • To assess for iodine-avid metastatic disease • When the results may alter the decision to treat • Prior to administration of RAI therapy	• Whole-Body Thyroid Nuclear scan (CPT® 78018) ◦ CPT® 78020 as an add-on test to evaluate the degree of iodine uptake AND/OR • SPECT (CPT® 78803, or CPT® 78831), OR SPECT/CT Hybrid study (CPT® 78830, or CPT® 78832)

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Follicular, Papillary, and Hürthle Cell (Oncocytic) Carcinomas	Medically Necessary Imaging Study
Skeletal pain	• Bone scan (CPT® 78306) See also: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes • Whole-Body Thyroid Nuclear scan (CPT® 78018) ◦ CPT® 78020 as an add-on test to evaluate the degree of iodine uptake AND/OR • SPECT (CPT® 78803 or CPT® 78831), OR SPECT/CT Hybrid study (CPT® 78830, or CPT® 78832)
Suspicious findings on chest x-ray, US, or substernal extension of mass	• CT Chest without contrast (CPT® 71250)
All other individuals	• Routine preoperative advanced imaging is not medically necessary

Medullary Thyroid Carcinomas	Medically Necessary Imaging Study
ANY of the following: • Elevated CEA levels • Calcitonin level >300pg/mL • Positive lymph nodes	ANY or ALL of the following: • CT Neck with contrast (CPT® 70491) • CT Chest with contrast (CPT® 71260) • CT Abdomen with contrast (CPT® 74160) **or** CT Abdomen without and with contrast (CPT® 74170) • MRI Abdomen without and with contrast (CPT® 74183) • Bone scan (CPT® 78306) see also: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes

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Medullary Thyroid Carcinomas	Medically Necessary Imaging Study
Skeletal pain	• Bone scan (CPT® 78306) see also: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes
Inconclusive findings on conventional imaging	• ^{68}Gallium-labeled PET/CT (CPT® 78815)

Anaplastic/Poorly Differentiated Thyroid Carcinomas	Medically Necessary Imaging Study
All	ANY or ALL of the following: • CT Neck with contrast (CPT® 70491) or MRI Orbit, Face, Neck without and with contrast (CPT® 70543) • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • FDG PET/CT (CPT® 78815) • CT Head with contrast (CPT® 70460)
Skeletal pain	• Bone scan see also: **Nuclear Medicine (NM) Imaging (ONC-1.3)** in Oncology

Evidence Discussion

For follicular, papillary and Hurthle cell carcinomas, focused imaging of the neck using contrast enhanced CT or MRI is recommended to assess extent of local disease and guide pre-surgical planning. CT Chest with contrast may be indicated based on these results to include substernal extension of the thyroid mass. There are no established guidelines regarding the minimum gap between contrast enhanced CT with iodinated contrast agents and iodine-131/123 for whole body scintigraphy (WBS) in the treatment of residual disease and distant metastases, with majority recommendation of a gap of 4 weeks and 2 months. In the post-thyroidectomy setting, WBS is recommended to assess for either extent of thyroid remnant, when results may alter the decision to treat and prior to administration of radioactive iodine (RAI) therapy. In the presence of skeletal pain, whole body bone scan or WBS to assess for osseous metastases. Medullary thyroid carcinoma is frequently aggressive with 48% of patients having localized disease, 35% with tumors extending beyond the thyroid into surrounding tissues or regional nodes and 13% with distant metastases typically to the lung, liver

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or bones. Due to these concerns, more extensive staging is indicated that includes contrast enhanced CT of neck, chest and abdomen as well as bone scan if there are elevated CEA levels, calcitonin level >300 pg/nL or positive lymph nodes. Skeletal pain can be imaged with bone scan. Gallium-68 labelled dotatate PET/CT or if not available Indium-111-pentetreotide (Octreoscan) is useful due to high expression of somatostatin receptors in MTC and is indicated if conventional imaging is inconclusive due to its high sensitivity compared to other imaging modalities especially if calcitonin levels are >500. Anaplastic thyroid carcinoma is the most aggressive variant of thyroid cancer with distant metastases in over 50% of cases at presentation most commonly involving the lung, bone and brain with 5 year survival <10%. Complete staging with CT Neck, Chest, Abdomen and Pelvis is supported in conjunction with FDG PET/CT as the diagnostic contrasted CTs may better elucidate vascular and airway involvement. MRI of the brain is also indicated.[4,6,9,10,13]

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Thyroid Cancer – Restaging/Recurrence (ONC-6.3)

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Follicular, Papillary, and Hürthle Cell (Oncocytic) Carcinomas	Medically Necessary Imaging Study
Post-thyroidectomy, if gross residual disease	ONE of the following: • MRI Neck without contrast (CPT® 70540) • MRI Neck without and with contrast (CPT® 70543) • CT Neck with contrast (CPT® 70491)
Within 2 weeks (ideally 7 to 10 days) following the administration of Radioactive Iodine therapy	• Whole-body thyroid nuclear scan (CPT® 78018) • The following may be approved as an add-on test: ◦ CPT® 78020 to evaluate the degree of iodine uptake ◦ SPECT (CPT® 78803, or CPT® 78831), or SPECT/CT Hybrid study (CPT® 78830, or CPT® 78832)
ANY of the following: • Recurrence documented by biopsy • Increasing thyroglobulin level without Thyrogen® stimulation • Thyroglobulin level >2 ng/mL or higher than previous after Thyrogen® stimulation • Anti-thyroglobulin antibody present • Evidence of residual thyroid tissue on ultrasound or physical exam after thyroidectomy or ablation	ALL of the following: • CT Neck with contrast (CPT® 70491) or MRI Neck without and with contrast (CPT® 70543) • CT Chest with contrast (CPT® 71260) • CT with contrast of any symptomatic body area • Whole-body Thyroid Nuclear Scan (CPT® 78018) ◦ As an add-on test: ▪ CPT® 78020 to evaluate the degree of iodine uptake ▪ SPECT (CPT® 78803 or CPT® 78831), or SPECT/CT Hybrid study (CPT® 78830, or CPT® 78832)

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Follicular, Papillary, and Hürthle Cell (Oncocytic) Carcinomas	Medically Necessary Imaging Study
ANY of the following: • Rising thyroglobulin level with negative CT scans AND radioiodine scan • Inconclusive findings on conventional imaging (CT scans and radioiodine scan) • Known radioiodine-refractory disease and CT scans are negative or inconclusive	• FDG PET/CT (CPT® 78815)
Measurable metastatic disease on systemic therapy (no more often than every 2 cycles)	• CT Chest with contrast (CPT® 71260) • CT with contrast of affected or symptomatic body area

Medullary Thyroid Carcinoma	Medically Necessary Imaging Study
ANY of the following: • Elevated CEA levels • Calcitonin level ≥150 pg/mL • Signs or symptoms of recurrence	ANY or ALL of the following: • CT Neck with contrast (CPT® 70491) or MRI Neck without and with contrast (CPT® 70543) • CT Chest with contrast (CPT® 71260) • CT Abdomen either with (CPT® 74160) or without and with contrast (CPT® 74170) • Bone scan (CPT® 78306) See also: **Nuclear Medicine (NM) Imaging (ONC-1.3)** in Oncology
Inconclusive conventional imaging with calcitonin ≥150 pg per mL	• ^{68}Gallium-labeled DOTATATE PET/CT (CPT® 78815)
Calcitonin level >500	ONE of the following: • MRI Abdomen without and with contrast (CPT® 74183) • Whole-body MRI (CPT® 76498)

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Anaplastic/Poorly Differentiated Thyroid Carcinoma	Medically Necessary Imaging Study
Measurable metastatic disease on systemic treatment	Any of the following every 2 cycles (usually every 6-8 weeks): • CT Neck with contrast (CPT® 70491) • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT of any other involved/symptomatic sites
Signs or symptoms of recurrence	ONE of the following combinations, not both: • CT Neck with contrast (CPT® 70491), CT Chest with contrast (CPT® 71260), CT Abdomen and Pelvis with contrast (CPT® 74177) **OR** • FDG PET/CT (CPT® 78815) In addition to one of the above studies: • MRI Brain without and with contrast (CPT® 70553)

Evidence Discussion

For Follicular, Papillary and Hurthle Cell carcinomas, CT or MRI neck can be performed if gross residual disease is found in the neck post-thyroidectomy. RAI therapy is administered after thyroidectomy for several reasons to include remnant ablation, treat presumed foci of neoplastic cells and/or treat persistent or recurrent disease. Within 2 weeks of treatment, WBS is indicated to stage the disease and document the I-131 avidity of any structural lesion. Follow-up is usually a combination of exam, laboratories (thyroglobulin and anti-thyroglobulin antibody levels) and ultrasound. If there is concern for recurrence, CT of the neck/chest as well as any symptomatic body area along with WBS should be performed to complete restaging. In the setting of rising thyroglobulin level with negative conventional imaging, inconclusive conventional imaging or known RAI-refractory disease with negative/inconclusive CT scans, FDG PET/CT can be performed due to its high sensitivity (94%) and specificity (80% to 84%) compared to conventional imaging. FDG uptake is associated with a worse prognosis and refractoriness to RAI therapy. Initial imaging for MTC recurrence based on elevated CEA levels, calcitonin level >150 pg/mL or signs/symptoms of recurrence should

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undergo CT or MRI Neck, CT Chest and Abdomen, and bone scan. If this imaging is inconclusive and calcitonin is >150, Gallium-68 labeled dotatate PET/CT or if not available Indium-111-pentetreotide (Octreoscan) is indicated as outlined in the initial work-up/staging section. In individuals with very high calcitonin levels, whole-body MRI or MRI liver are useful for imaging evaluation to evaluate for metastases.[1] Initial imaging for ATC recurrence includes either CT Neck, Chest, Abdomen and Pelvis or FDG PET/CT as well as MRI Brain due to its aggressive and widespread behavior. For individuals on systemic therapy, CT of neck/chest/abdomen/pelvis with any additional involved/symptomatic sites can be done every 2 cycles.[11]

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Thyroid Cancer – Surveillance/Follow-up (ONC-6.4)

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Follicular, Papillary, and Hürthle Cell (Oncocytic) Carcinomas	Medically Necessary Imaging Study
Individuals being monitored on active surveillance	• Neck ultrasound (CPT® 76536) every 6 months for 2 years, and then annually thereafter
All other individuals post-treatment	• Neck ultrasound (CPT® 76536) once at 6-12 months post-treatment, and then annually thereafter
For individuals with ANY of the following: • Node positive disease • RAI-avid metastases	• Whole-body Thyroid Nuclear Scan annually (CPT® 78018) ◦ CPT® 78020 as an add-on test to evaluate the degree of iodine uptake AND/OR • SPECT (CPT® 78803, or CPT® 78831), OR SPECT/CT Hybrid study (CPT® 78830, or CPT® 78832)

Medullary Carcinomas	Medically Necessary Imaging Study
All individuals	• CEA and calcitonin are required for monitoring medullary carcinomas • Routine surveillance imaging is not medically necessary

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Anaplastic/Poorly Differentiated Thyroid Carcinomas	Medically Necessary Imaging Study
All individuals	Every 3 months for 2 years: • CT Neck with contrast (CPT® 70491) • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • MRI Brain without and with contrast (CPT® 70553)

Evidence Discussion

For follicular, papillary and Hurthle cell carcinomas, all individuals are monitored with ultrasound either every 6 months for 2 years then annually (active surveillance) or once at 6-12 months then annually (post-treatment). For node positive disease or RAI-avid metastases, WBS annually. MTC is monitored with CEA and calcitonin levels with no routine imaging indicated. ATC requires close monitoring with CT neck/chest/abdomen/pelvis and MRI Brain every 3 months for 2 years as the vast majority of relapses occur within this timeframe.[1,9]

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Small Cell Lung Cancer (ONC-7)

Guideline

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Small Cell Lung Cancer – General Considerations (ONC-7.0)

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- Combined histologies of small and non-small cell are considered small cell lung cancer. Use this guideline for imaging recommendations for small and large cell high-grade (poorly differentiated) neuroendocrine tumors of the lung.
- Imaging is presently guided by traditional staging of limited or extensive disease.
  - Extensive stage is either metastatic disease or an extent which cannot be encompassed by a single radiotherapy portal.
  - Limited staging is confined to one side of the chest.
- Individuals treated curatively for SCLC are at increased risk for developing a second lung cancer. If new lung nodule is seen on imaging without any evidence of other systemic disease, follow **Lung Metastases (ONC-31.1)** for work-up of nodule.
- For carcinoid (low-grade neuroendocrine tumors) of the lung, see: **Neuroendocrine Cancers and Adrenal Tumors (ONC-15)**.

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Small Cell Lung Cancer – Suspected/ Diagnosis (ONC-7.1)

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Indication	Medically Necessary Imaging Study
• Abnormal chest x-ray or clinical suspicion remains high despite a normal chest x-ray in symptomatic individual	• CT Chest without contrast (CPT® 71250) **or** • CT Chest with contrast (CPT® 71260)
• Pulmonary nodule <8 mm in size noted on CT Chest	• See: **Incidental Pulmonary Nodules Detected on CT Images (CH-16.2)** in the Chest Imaging Guidelines
• Pulmonary nodule 8 mm (0.8 cm) to 30 mm (3 cm) seen on CT Chest or MRI Chest	• PET/CT (CPT® 78815) • PET is Positive: Qualifies as initial staging PET/CT
• Pulmonary mass 31 mm (3.1 cm) or greater seen on CT or MRI	• PET/CT (CPT® 78815) prior to biopsy if ONE or MORE of the following applies: ◦ Definitive treatment with resection or radiation will be utilized instead of biopsy if PET confirms limited disease ◦ Multiple possible biopsy options are present within the chest and PET findings will be used to determine the most favorable biopsy site • Biopsy is indicated prior to PET imaging for all other indications in pulmonary masses ≥31 mm (3.1 cm) in size
• Mediastinal/Hilar Mass	See: **Lymphadenopathy (CH-2)** in the Chest Imaging Guidelines
• Paraneoplastic syndrome suspected	See: **Paraneoplastic Syndromes (ONC-30.3)**

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Evidence Discussion

For individuals with suspected lung cancer and an abnormal chest x-ray or a high suspicion for lung cancer with symptoms of lung cancer, a CT Chest is indicated, with or without contrast. If a PET/CT is performed in the workup of a pulmonary nodule and is positive, it qualifies as the initial staging PET. The radiotracer supported for PET/CT for lung cancer is 18-FDG.[6,9] While some small cell lung cancer (SCLC) has a neuroendocrine component, the sensitivity, specificity and predictive value of dotatate PET/CT are uncertain at this time and dotatate PET is not supported.[6,9] Lesions 31mm or greater are considered masses rather than nodules, and should be biopsied rather than re-imaged with PET/CT.[5]

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Small Cell Lung Cancer – Initial Work-up/ Staging (ONC-7.2)

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Indication	Medically Necessary Imaging Study
Initial staging	ANY or ALL of the following: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • MRI Brain without and with contrast (CPT® 70553) • Bone scan (CPT® 78306), if PET/CT not being done or not available (See also: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes)
• To confirm the extent of disease when initial CT Chest/Abdomen/Pelvis and MRI Brain indicate limited stage disease (confined to one side of the chest) • To evaluate inconclusive findings on conventional imaging	• PET/CT (CPT® 78815)
• Inconclusive bone findings on PET/CT or bone scan	• MRI without and with contrast of the involved body site

Evidence Discussion

SCLC has widespread distant metastatic potential, with 2/3 of individuals having metastatic disease at diagnosis and 10% to 15% including central nervous system disease.[6,9] Diagnostic contrasted CTs of chest, abdomen and pelvis as well as MRI Brain with and without contrast are supported.[1] If PET has been completed in the pulmonary nodule workup, a repeat PET/CT is generally not supported. If a PET/CT was done prior to diagnosis and conventional imaging clearly shows extensive stage disease, a PET/CT does not change management. However, if a PET/CT was not done prior to diagnosis, a PET/CT is supported to confirm limited stage disease prior to treatment, as FDG PET/CT changes stage versus conventional imaging in up to 25% of

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individuals.[6,9] Bony metastatic disease is not unusual in SCLC; thus, evaluation for bony metastatic disease is supported .[1,6]

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Small Cell Lung Cancer – Restaging/ Recurrence (ONC-7.3)

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Indication	Medically Necessary Imaging Study
Treatment response in individuals treated with sequential chemotherapy-radiation or chemotherapy alone* *For individuals receiving systemic therapy and concurrent radiation therapy, response assessment is recommended only after completion of initial therapy (see box below).	After every 2 cycles, ANY or ALL of the following: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • MRI Brain without and with contrast (CPT® 70553) for measurable brain metastases being treated with systemic therapy • Bone scan (CPT® 78306) (See also: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes) • PET is not indicated for evaluation of treatment response in SCLC but can be considered on a case-by-case basis.
Following completion of planned treatment: • Chemoradiation • Adjuvant chemotherapy • Radiation	ANY or ALL of the following: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • MRI Brain without and with contrast (CPT® 70553) for measurable brain metastases being treated with systemic therapy • Bone scan (CPT® 78306) (See also: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3**) for additional bone scan codes)

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Indication	Medically Necessary Imaging Study
Restaging (suspected recurrence)	ANY or ALL of the following: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • MRI Brain without and with contrast (CPT® 70553) • Bone scan (CPT® 78306) (See: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes) • PET is not indicated for evaluation of recurrent SCLC but can be considered on a case-by-case basis.
For response assessment following primary treatment	• MRI Brain without and with contrast (CPT® 70553)

Evidence Discussion

Conventional imaging with contrasted CT Chest, Abdomen and Pelvis is supported every 2 cycles of chemotherapy and at the end of chemoradiation. MRI Brain with and without contrast is supported when there is measurable CNS disease being treated with systemic therapy. If prophylactic cranial irradiation (PCI) is planned, an MRI brain is supported at end of initial treatment as some individuals will harbor asymptomatic brain metastases and will require different management, and PCI would expose the individual to radiation doses and neurotoxicity without benefit.[1,7] CT Chest, Abdomen and Pelvis as well as MRI Brain and bone scan are supported if recurrence is suspected. Further literature is emerging to determine the role of FDG PET-CT for treatment response and suspected recurrence; these guidelines do not routinely support PET/CT for treatment response or suspected recurrence of SCLC, but provide flexibility on a case by case basis, particularly for individuals with bony metastatic disease.[1,8,9]

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Small Cell Lung Cancer – Surveillance/ Follow-up ONC-7.4

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Indication	Medically Necessary Imaging Study
Limited stage SCLC	Every 3 months for two years, every 6 months during year three, and then annually: • CT Chest without (CPT® 71250) or CT Chest with (CPT® 71260) contrast • CT Abdomen and Pelvis with contrast (CPT® 74177)
Extensive stage SCLC	Every 2 months for one year, every 3 months for two years, every 6 months for two years, and then annually: • CT Chest without (CPT® 71250) or CT Chest with (CPT® 71260) contrast • CT Abdomen and Pelvis with contrast (CPT® 74177)
Screening for brain metastases, regardless of PCI status	• MRI Brain without and with contrast (CPT® 70553) every 3 months for 1 year and then every 6 months thereafter
Surveillance of known and/or treated brain metastases	• See: **Brain Metastases (ONC-31.3)**
New lung nodule(s)	• See: **Lung Metastases (ONC-31.1)**

Evidence Discussion

Surveillance with CT contrasted chest, abdomen and pelvis is supported. MRI chest is less sensitive than CT chest and usually not supported as a substitution for lung cancer. Follow up is supported more frequently in the first two years post treatment, as that is when recurrence is most common.[1,6,9] The surveillance timeframe is determined by the initial extent of disease. For those with limited stage disease, these guidelines support the above CT imaging every 3 months for 2 years, every 6 months during year 3, and then annually. For those with extensive stage disease, imaging with above CTs is supported every 2 months for 1 year, every 3 months for two years, every 6 months for 2 years, then annually. This is in alignment with the follow up visit timeframe recommended by NCCN. Up to 30% of individuals develop metastatic disease to the

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brain. Screening for brain metastases is supported to allow early treatment of brain metastases prior to potentially impairing neurologic symptoms. MRI is preferred over CT for its increased sensitivity and specificity, at an interval of every 3 months for 1 year then every 6 months indefinitely.[1,7,9] PET/CT is not supported for surveillance due to excessive radiation exposure, false positive incidental findings, and financial toxicity.

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Non-Small Cell Lung Cancer (ONC-8)

Guideline

Non-Small Cell Lung Cancer – General Considerations (ONC-8.0)
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Non-Small Cell Lung Cancer – Suspected/Diagnosis (ONC-8.2)
Non-Small Cell Lung Cancer – Initial Work-up/Staging (ONC-8.3)
Non-Small Cell Lung Cancer – Restaging/Recurrence (ONC-8.4)
Non-Small Cell Lung Cancer – Surveillance/Follow-up (ONC-8.5)
References (ONC-8)

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Non-Small Cell Lung Cancer – General Considerations (ONC-8.0)

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- Non-small cell lung cancer includes adenocarcinoma, squamous cell carcinoma, adenosquamous and large cell tumors.
- See: **Bronchopulmonary or Thymic Carcinoid – Initial Staging (ONC-15.6)** for evaluation of low-grade neuroendocrine tumors (carcinoid) of the lung.
- See: **Small Cell Lung Cancer (ONC-7)** for evaluation of high-grade small cell and large cell neuroendocrine tumors of the lung.
- PET/CT may be considered to confirm solitary focus of extra-pulmonary metastatic disease (i.e., brain or adrenal) if the individual is being considered for an aggressive treatment for oligometastatic disease.

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Non-Small Cell Lung Cancer – Asymptomatic Screening (ONC-8.1)

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- See: **Lung Cancer Screening (CH-33)** in the Chest Imaging Guidelines for criteria for Low-dose CT Chest for lung cancer screening.

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Non-Small Cell Lung Cancer – Suspected/Diagnosis (ONC-8.2)

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Indication	Medically Necessary Imaging Study
Abnormal chest x-ray or clinical suspicion remains high despite a normal chest x-ray in symptomatic individual	• CT Chest without contrast (CPT® 71250) **or** • CT Chest with contrast (CPT® 71260)
Pulmonary nodule <8 mm in size noted on CT Chest	• See: **Incidental Pulmonary Nodules Detected on CT Images (CH-16.2)** in the Chest Imaging Guidelines
Pulmonary nodule 8 mm (0.8 cm) to 30 mm (3 cm) seen on CT Chest or MRI Chest	• PET/CT (CPT® 78815) • If PET is Positive: Qualifies as initial staging PET/CT
Pulmonary mass 31 mm (3.1 cm) or greater seen on CT or MRI	• PET/CT (CPT® 78815) prior to biopsy if ONE or MORE of the following applies: ◦ Definitive treatment with resection or radiation will be utilized instead of biopsy if PET confirms limited disease ◦ Multiple possible biopsy options are present within the chest and PET findings will be used to determine the most favorable biopsy site • Biopsy is indicated prior to PET imaging for all other indications in pulmonary masses ≥31 mm (3.1 cm) in size
Mediastinal/Hilar Lymphadenopathy	See: **Mediastinal Lymphadenopathy (CH-2.3)** in the Chest Imaging Guidelines
Mediastinal/Hilar Mass	See: **Mediastinal Mass (CH-20)** in the Chest Imaging Guidelines
Paraneoplastic syndrome suspected	See: **Paraneoplastic Syndromes (ONC-30.3)**

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Evidence Discussion

For individuals with suspected lung cancer and an abnormal chest x-ray or a high suspicion for lung cancer with symptoms of lung cancer, a CT Chest is indicated, with or without contrast. If a PET/CT is performed in the workup of a pulmonary nodule and is positive, it qualifies as the initial staging PET. The radiotracer supported for PET/CT for lung cancer is 18-FDG.[3,14] Lesions 31mm or greater are considered masses rather than nodules.*3* There is no clear evidence for PET/CT over biopsy in this case. Generally, masses should be biopsied rather than re-imaged. PET/CT is supported if definitive treatment with resection or radiation will be utilized instead of biopsy (if PET confirms limited disease), or if multiple biopsy sites are present within the chest and PET findings will be used to determine the most favorable biopsy site. This maximizes safety when making decisions regarding invasive procedures.

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Non-Small Cell Lung Cancer – Initial Work-up/Staging (ONC-8.3)

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Indication	Medically Necessary Imaging Study
All individuals	ANY or ALL of the following: • CT Chest with contrast (CPT® 71260) • CT Abdomen with contrast (CPT® 74160) ◦ CT Abdomen can be omitted if CT Chest report clearly documents upper abdomen through level of adrenals • PET/CT (CPT® 78815) (if not already completed prior to histological diagnosis) • Bone scan (CPT® 78306, if PET/CT not being done) See also: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes
Stage IB-IV disease	• MRI Brain without and with contrast (CPT® 70553) ◦ If MRI Brain is contraindicated or not available, CT Head with contrast (CPT® 70460) or CT Head without and with contrast (CPT® 70470)
Superior sulcus (Pancoast) tumor suspected	ANY or ALL of the following: • MRI Chest without and with contrast (CPT® 71552) • MRI Cervical Spine without and with contrast (CPT® 72156) • MRI Thoracic Spine without and with contrast (CPT® 72157)

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Evidence Discussion

CT Chest and upper abdomen to the level of the adrenals is supported for initial staging, as liver and adrenal metastatic disease are common in NSCLC. Pelvic disease is rare and imaging of the pelvis without pelvic symptoms is not recommended by NCCN.[1] FDG PET-CT is supported by NCCN in all individuals.[1]

Over 10% of individuals with stage III or IV disease present with metastatic disease to the brain, and 4% to 5% of individuals with stage II disease. MRI Brain with and without contrast has a higher detection rate for metastatic disease to the brain than CT, and is indicated in all individuals with stage II-IV disease.[1] For individuals with stage IB disease, MRI Brain with and without contrast is optional in this setting but can be considered to prevent under-staging and under-treatment, since a small number of individuals with apparent stage I disease and no CNS symptoms will have occult brain lesions and will require additional therapies.[1,14]

For individuals with superior sulcus (Pancoast) tumor, MRI Chest and MRI Cervical and Thoracic Spine with and without contrast have higher specificity for chest wall invasion, neurologic involvement, and fibrosis than CT alone, and are supported in addition to the imaging stated above.[1,13]

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Non-Small Cell Lung Cancer – Restaging/Recurrence (ONC-8.4)

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Indication	Medically Necessary Imaging Study
Stage I or II individuals who undergo definitive local treatment with surgery, radiation, or radiosurgery	• Restaging imaging is not medically necessary. See: **Surveillance/Follow-up (ONC-8.5)**
Measurable disease, undergoing active treatment	ANY or ALL of the following every 2 cycles: • CT Chest with (CPT® 71260) **or** CT Chest without contrast (CPT® 71250) • CT Abdomen with contrast (CPT® 74160) ◦ CT Abdomen and Pelvis with contrast (CPT® 74177) for known pelvic disease or pelvic symptoms • MRI Brain without and with contrast (CPT® 70553) for measurable brain metastases being treated with systemic therapy
ANY of the following: • After neoadjuvant treatment for evaluation of surgical resectability • Prior to starting adjuvant therapy • Inadequately resected disease	• CT Chest with (CPT® 71260) **or** CT Chest without contrast (CPT® 71250)
Suspected recurrence	ANY or ALL of the following: • CT Chest with (CPT® 71260) **or** CT Chest without contrast (CPT® 71250) • CT Abdomen with contrast (CPT® 74160) ◦ CT Abdomen and Pelvis with contrast (CPT® 74177) for known pelvic disease or pelvic symptoms

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Indication	Medically Necessary Imaging Study
Newly identified lung nodule(s)	• See: **Lung Metastases (ONC-31.1)** for new nodule evaluation
ANY of the following: • Suspected/biopsy proven recurrence localized to the chest cavity • Inconclusive findings conventional imaging • To differentiate tumor from radiation scar/fibrosis • Stage IV with oligometastatic disease on conventional imaging and individual is a candidate for aggressive surgical resection or other localized treatment of metastases with a curative intent	• PET/CT (CPT® 78815)
ANY of the following: • Following a demonstrated adequate response to neoadjuvant therapy if intracranial disease will preclude surgery • Documented recurrence/progression • New or worsening neurological signs or symptoms	• MRI Brain without and with contrast (CPT® 70553)

Evidence Discussion

In alignment with NCCN, CT Chest and Abdomen with contrast are supported every two cycles, with pelvic imaging only for a history of pelvic disease or new pelvic symptoms. These are also supported at any time for clinically suspected recurrence. MRI Brain with and without contrast is supported every 2 cycles for individuals with known brain metastases being treated with systemic therapy, or at any time for individuals with new neurologic symptoms or documented systemic progression.[1] An additional CT chest is supported if requested after neoadjuvant therapy to evaluate for resectability, in the interest of safe resection. CT is also supported post-operatively to assess baseline prior to starting adjuvant therapy, in alignment with NCCN.[1]

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Non-Small Cell Lung Cancer – Surveillance/Follow-up (ONC-8.5)

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Indication	Medically Necessary Imaging Study
Stage I-II (treatment including surgery and/ or chemotherapy, but no radiation)	• CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) every 6 months for 3 years and then annually
Stage I-II treated with radiation therapy Stage III-IV (metastatic sites treated with definitive intent)	• CT Chest with contrast (CPT® 71260) **or** CT Chest without contrast (CPT® 71250) every 3-6 months for 3 years, every 6 months for 2 years and then annually
New lung nodule	• See: **Lung Metastases (ONC-31.1)**

Evidence Discussion

CT Chest with or without contrast is recommended by national guidelines every 6 months for 3 years and then annually for individuals with stage I or II disease. To prevent under-treatment, individuals treated with radiation who have residual abnormalities on imaging may undergo more frequent imaging every 3-6 months for the first year then every 6 months for 2 years, then annually thereafter. Individuals with stage II disease or definitively treated metastatic disease are at higher risk for relapse particularly in the first 2 years, and NCCN recommended CT Chest every 3-6 months for 3 years, every 6 months for 2 years, then annually. Asymptomatic abdominal and pelvic imaging exposes to radiation with low-yield for metastatic disease detection and is not supported. FDG-PET is not supported for surveillance due to excessive false positive rates, radiation exposure, and increased risk of unnecessary procedures for incidental false positive findings. MRI Brain for asymptomatic surveillance is low yield in asymptomatic NSCLC surveillance and is not routinely recommended.[1,2]

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Esophageal and GE Junction Cancer (ONC-9)

Guideline

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Esophageal and GE Junction Cancer – Initial Work-up/Staging (ONC-9.2)
Esophageal and GE Junction Cancer – Restaging/Recurrence (ONC-9.3)
Esophageal and GE Junction Cancer – Surveillance/Follow-up (ONC-9.4)
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Esophageal and GE Junction Cancer – General Considerations (ONC-9.0)

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- Imaging for esophageal cancer is determined by cell type and in which third of the esophagus it occurs.
- Cancers of the upper and middle third are usually squamous cell and are highly associated with tobacco and alcohol abuse.
- Cancers of the gastroesophageal (GE) junction are treated as lower third cancers. Lower third cancers are usually adenocarcinomas; 62% of these arise in the setting of Barrett's esophagus, a condition associated with high body mass index (BMI).

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Esophageal and GE Junction Cancer – Suspected/Diagnosis (ONC-9.1)

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- See: **Dysphagia and Upper Digestive Tract Disorders (NECK-3.1)** in the Neck Imaging Guidelines for evaluation of suspected esophageal malignancy.

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Esophageal and GE Junction Cancer – Initial Work-up/Staging (ONC-9.2)

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Indication	Medically Necessary Imaging Study
Biopsy proven	• CT Chest (CPT® 71260) and CT Abdomen (CPT® 74160) with contrast ◦ CT Abdomen and Pelvis with contrast (CPT® 74177) instead of CT Abdomen if there are pelvic signs or symptoms
In addition to the above, for any of the following: • Upper 1/3 of esophagus • Neck mass	• CT Neck with contrast (CPT® 70491)
If no evidence of metastatic disease on conventional imaging	• PET/CT (CPT® 78815)

Evidence Discussion

- Upon initial diagnosis of cancer, CT Chest/Abdomen is recommended with the addition of pelvis if there are signs/symptoms of disease. NCCN stated that "CT can be used to determine the location of the primary tumor and its proximity to other structures".[1]
- Cancers diagnosed in the upper 1/3 of the esophagus should also obtain CT of the neck due to concern for nodal spread.
- If CT imaging does not show evidence of metastatic disease, PET/CT is indicated to assess for occult metastases to help finalize treatment options (curative versus palliative). PET/CT is not sensitive for locoregional nodal assessment as often these nodes are obscured by metabolic activity in the primary tumor but is more sensitive than CT for detecting distant metastases.
- NCCN also stated that PET/CT has "limited ability to ability to differentiate between cT1, cT2, and cT3 tumors. Therefore, CT should be performed as part of initial workup (as well as pelvic CT scan with contrast if clinically indicated) while FDG-PET/CT should be reserved for individuals with no evidence of M1 disease".[1]

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Esophageal and GE Junction Cancer – Restaging/Recurrence (ONC-9.3)

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Indication	Medically Necessary Imaging Study
After primary chemoradiation therapy prior to surgery	Any ONE of the following, not both: • PET/CT (CPT® 78815) no sooner than 5 weeks post completion of radiation therapy OR • CT Chest (CPT® 71260) and CT Abdomen (CPT® 74160) with contrast ◦ CT Abdomen and Pelvis with contrast (CPT® 74177) instead of CT Abdomen if there are pelvic signs or symptoms or known pelvic disease
Post-surgical resection	• See: **Surveillance/Follow-up (ONC-9.4)**
Monitoring response to chemotherapy for stage IV/ metastatic disease	Every 2 cycles of treatment (~every 6-8 weeks): • CT Abdomen with contrast (CPT® 74160) • CT Chest with contrast (CPT® 71260)
• If conventional imaging is inconclusive **or** • Salvage surgical candidate with recurrence and no metastatic disease documented by conventional imaging	• PET/CT (CPT® 78815)
For ANY of the following: • Signs or symptoms of recurrence • Biopsy proven on follow-up endoscopy • Recurrence suggested by other imaging (i.e. chest x-ray or barium swallow)	• CT Chest (CPT® 71260) and CT Abdomen (CPT® 74160) with contrast

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Indication	Medically Necessary Imaging Study
If previously involved or new signs or symptoms	• CT Pelvis with contrast (CPT® 72193) and/or CT Neck with contrast (CPT® 70491)

Evidence Discussion

- Primary treatment typically involves chemoradiotherapy alone, surgery alone or both.
- After primary chemoradiation has been completed and prior to surgery, one of the following is recommended: CT Chest/Abdomen or PET/CT, with the latter ideally no sooner than 5 weeks after completion of radiation to minimize risk of false positives.
- Post-surgical resection is handled as disease surveillance.
- For Stage IV disease on chemotherapy, CT Chest/Abdomen indicated every 2 cycles.
- If conventional imaging is inconclusive or the member is a candidate for salvage surgery upon recurrence with no evidence of metastatic disease, PET/CT is indicated.
- CT Chest/Abdomen for signs/symptoms of recurrence, biopsy proven recurrence on follow-up endoscopy and recurrence suggested by other imaging.
- CT imaging of any appropriate area (e.g. neck, pelvis) if new signs/symptoms or known previous involvement.[1]

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Esophageal and GE Junction Cancer – Surveillance/Follow-up (ONC-9.4)

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Indication	Medically Necessary Imaging Study
Stage 0-IA (Tis, T1a) disease	• No routine advanced imaging
Stage IB (T1b)-III disease	• CT Chest (CPT® 71260) and CT Abdomen (CPT® 74160) with contrast every 6 months for 2 years and then annually for 3 more years
Stage IV disease	• See: **Phases of Oncology Imaging and General Phase-Related Considerations (ONC-1.2)**

Evidence Discussion

- Stage 0-IA (Tis, T1a): No routine advanced imaging indicated. Fully treated Tis and T1aN0 disease have prognoses that approximate a non-cancer cohort.[1]
- Stage IB (T1b): CT Chest/Abdomen with contrast annually for 3 years. T1b does not perform as well as fully treated Tis and T1aN0 disease, thus supporting current recommendations.[1]
- Stage II-III: CT Chest/Abdomen every 6 months for 2 years then annually for 3 years.[1]
- Stage IV: CT Chest/Abdomen (additional sites as clinically indicated) every 3 months while on maintenance therapy or every 3 months up to 5 years if being monitored off therapy.[1]

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References (ONC-9)

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Other Thoracic Tumors (ONC-10)

Guideline

Malignant Pleural Mesothelioma – Suspected/Diagnosis (ONC-10.1)
Malignant Pleural Mesothelioma – Initial Work-up/Staging (ONC-10.2)
Malignant Pleural Mesothelioma – Restaging (ONC-10.3)
Malignant Pleural Mesothelioma – Surveillance (ONC-10.4)
Thymoma and Thymic Carcinoma – Suspected/Diagnosis (ONC-10.5)
Thymoma and Thymic Carcinoma – Initial Work-up/Staging (ONC-10.6)
Thymoma and Thymic Carcinoma – Restaging (ONC-10.7)
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Malignant Pleural Mesothelioma – Suspected/Diagnosis (ONC-10.1)

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- See: **Asbestos Exposure (CH-9.1)** in the Chest Imaging Guidelines for evaluation of suspected mesothelioma.

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Malignant Pleural Mesothelioma – Initial Work-up/Staging (ONC-10.2)

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Indication	Medically Necessary Imaging Study
Cytologically or pathologically proven	• CT Chest (CPT® 71260) **and** CT Abdomen (CPT® 74160) with contrast ◦ CT Abdomen and Pelvis with contrast (CPT® 74177)instead of CT Abdomen if there are pelvic signs or symptoms
For EITHER of the following: • No evidence of distant metastatic disease on CT imaging • Inconclusive conventional imaging	• PET/CT (CPT® 78815)
Suspicion of possible chest wall, spinal, diaphragmatic, or vascular involvement based on CT imaging	• MRI Chest without and with contrast (CPT® 71552)

Evidence Discussion

Contrasted CT Chest and CT Abdomen are supported for initial staging once mesothelioma is proven with lung fluid cytology or tissue biopsy. Contrast allows better evaluation of nodal disease in addition to parenchymal disease and offers improved characterization of direct extrapulmonary tumor invasion. MRI is inferior for parenchymal lung imaging thus CT is essential. Anatomic soft tissue detail, differentiation from progressive benign fibrosis, and brachiocephalic vascular involvement may be better demonstrated on MRI without and with contrast, so this study is supported for suspected chest wall, spine, diaphragm, or vascular involvement. The most common site of metastatic disease outside the chest is the liver, so CT Abdomen is an important part of

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the initial workup. However, pelvic disease is rare and pelvic CT exposes to additional radiation and is low yield in individuals without pelvic signs and symptoms. Pelvis may be added to contrasted CT in individuals with signs and symptoms of pelvic involvement, including direct abdominoperitoneal invasion. National Cancer Database review of over 40,000 individuals treated between 2004 and 2020 reveals that 50% of individuals are metastatic upon presentation.[17] Signs and symptoms of metastatic disease in body areas not addressed in ONC-10 may be imaged according to their respective sections in ONC-31, for which separate evidence summaries are provided.

PET/CT is not first line imaging for mesothelioma as it is inadequate for differentiating benign vs malignant changes in exposure-related progressive massive pulmonary fibrosis, but of which take up FDG in unpredictable fashions. Understaging of the primary site is common with PET/CT alone. Conventional imaging is essential. However, PET/CT is supported to confirm the absence of metastatic disease on conventional imaging (negative or inconclusive) prior to resection, as up to 29% of individuals initially identified as operable may be reclassified as inoperable due to identification of distant metastatic disease on PET/CT during pre-operative evaluation.[1]

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Malignant Pleural Mesothelioma – Restaging (ONC-10.3)

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Indication	Medically Necessary Imaging Study
Signs or symptoms of recurrence	• CT Chest (CPT® 71260) **and** CT Abdomen (CPT® 74160) with contrast ◦ CT Abdomen and Pelvis with contrast (CPT® 74177) instead of CT Abdomen if there are pelvic signs or symptoms
Treatment with chemotherapy	Every 2 cycles: • CT Chest (CPT® 71260) **and** CT Abdomen (CPT® 74160) with contrast ◦ CT Abdomen and Pelvis with contrast (CPT® 74177) instead of CT Abdomen if there are pelvic signs or symptoms
Following induction chemotherapy prior to surgical resection	• CT Chest (CPT® 71260) **and** CT Abdomen (CPT® 74160) with contrast ◦ CT Abdomen and Pelvis with contrast (CPT® 74177) instead of CT Abdomen if there are pelvic signs or symptoms • PET/CT (CPT® 78815) if no evidence of distant metastatic disease
Inconclusive CT Chest	• MRI Chest without and with contrast (CPT® 71552)

Evidence Discussion

For individuals on chemotherapy, contrasted CT of chest and abdomen are supported every 2 cycles. Pelvic imaging may be added for signs and symptoms of peritoneal/ pelvic disease or known pelvic/peritoneal disease as noted in the initial staging section. The same logic applies to any individuals with signs and symptoms of recurrence. For individuals receiving induction chemotherapy, CT Chest and Abdomen (with pelvis if previously reviewed indications are present) are supported at end of induction. Response is categorized by validated mRECIST criteria on CT. If there is no metastatic

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disease, this may again be confirmed with PET/CT prior to attempted resection, ensuring the patient is not subjected to futile invasive surgery when RT or further systemic therapy may be more appropriate. If CT Chest is inconclusive, MRI Chest without and with contrast is supported. MRI Chest may differentiate between treatment-related changes (fibrosis) and persistent mesothelioma, which is not well-differentiated on PET/CT as both may have unpredictable FDG uptake.[1,10-13,17]

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Malignant Pleural Mesothelioma – Surveillance (ONC-10.4)

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Indication	Medically Necessary Imaging Study
All	• CT Chest with contrast (CPT® 71260) and previously involved regions every 3 months for 2 years, then annually thereafter

Evidence Discussion

There is no clear consensus for surveillance imaging for malignant pleural mesothelioma, and NCCN offered no guidance on this topic. The European Society of Medical Oncology (ESMO) advised CT for surveillance without a specific timeframe.[13] Given the known value of CT in assessing primary mesothelioma and abdomino/peritoneal metastatic disease, these guidelines support CT for surveillance. The timeframe is based on National Cancer Database survival statistics for malignant pleural mesothelioma.[2] In review of 40,000+ individuals treated between 2004 and 2020, individuals undergoing surgery had a median survival time for 19.8 months, compared with 7.9 months in those who had not undergone surgery. The 2-year survival for those who underwent surgery was 44%, with 18% 2-year survival in unresectable disease. 5-year survival is 5% in unresected disease, and 16% in those who underwent surgery. These guidelines support CT Chest and Abdomen with contrast every 3 months for the first 2 years, then annually. As noted in the restaging section, CT imaging is always supported for new signs and symptoms.[1]

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Thymoma and Thymic Carcinoma – Suspected/Diagnosis (ONC-10.5)

ON.OT.0010.5.A

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- The proceeding guidelines are intended to be used for imaging of malignant mediastinal masses.
- See: **Mediastinal Mass (CH-20.1)** in the Chest Imaging Guidelines for evaluation of mediastinal mass without confirmation of malignancy.
- See: **Bronchopulmonary or Thymic Carcinoid – Initial Staging (ONC-15.6)** for imaging guidelines for thymic carcinoid.

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Thymoma and Thymic Carcinoma – Initial Work-up/Staging (ONC-10.6)

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Indication	Medically Necessary Imaging Study
Encapsulated or invasive limited disease	• CT Chest with contrast (CPT® 71260)
Extensive mediastinal involvement on CT Chest	• CT Abdomen with contrast (CPT® 74160) • CT Neck with contrast (CPT® 70491)
Inconclusive finding on CT	ONE of the following: • PET/CT (CPT® 78815) • MRI Chest without and with contrast (CPT® 71552)
Preoperative planning	• MRI Chest without and with contrast (CPT® 71552)
Thymic Carcinomas	• Image according to **Non-Small Cell Lung Cancer - Initial Work-up/Staging (ONC-8.3)**

Evidence Discussion

Thymomas and thymic carcinomas originate in the thymus and are epithelial tumors. Thymomas are rare tumors (though most common primary tumor of anterior mediastinum) that typically spread locally with 5-year survival rates of 90% while thymic carcinomas are very rare, more invasive and often present with metastases with 5-year survival rates of 55%.[3] Initial imaging for thymoma includes CT Chest with contrast that usually shows a well-defined rounded or oval mass without adenopathy. If there is extensive mediastinal involvement, CT Neck/Abdomen with contrast can be performed. If CT imaging is inconclusive, PET/CT or MRI Chest with and without contrast may be indicated, with MRI preferred in thymic carcinoma.[14,15] For preoperative planning, MRI Chest is also indicated.

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Thymoma and Thymic Carcinoma – Restaging (ONC-10.7)

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Indication	Medically Necessary Imaging Study
Adjuvant therapy following surgical resection	• Follow surveillance imaging
Following induction chemotherapy prior to surgical resection, if no evidence of metastatic disease	ONE of the following: • PET/CT (CPT® 78815) • CT Chest with contrast (CPT® 71260) • MRI Chest without and with contrast (CPT® 71552)
For suspected recurrence	• CT Chest with contrast (CPT® 71260)
Recurrence with extensive mediastinal involvement on CT Chest	• CT Abdomen with contrast (CPT® 74160) • CT Neck with contrast (CPT® 70491)
Inconclusive finding on CT	ONE of the following: • PET/CT (CPT® 78815) • MRI Chest without and with contrast (CPT® 71552)
Metastatic disease on chemotherapy	• CT Neck (CPT® 70491), CT Chest (CPT® 71260), and CT Abdomen (CPT® 74160) with contrast, every 2 cycles of therapy
Thymic carcinomas	• See: **Non-Small Cell Lung Cancer Restaging/ Recurrence (ONC-8.4)**

Evidence Discussion

If induction chemotherapy is given, PET/CT can be obtained prior to surgical resection as studies have shown a correlation of radiographic response to pathologic response to help guide resectability.[16] Chest imaging with CT or MRI are also accepted imaging choices for this purpose. For recurrence, CT Chest with CT Neck/Abdomen as clinically

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indicated. PET/CT or MRI Chest indicated if CT Chest is inconclusive. For individuals on chemotherapy for metastatic disease, CT Neck/Chest/Abdomen with contrast can be given every 2 cycles.[3]

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Thymoma and Thymic Carcinoma – Surveillance (ONC-10.8)

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Indication	Medically Necessary Imaging Study
Thymoma, R0 resection	• CT Chest with contrast (CPT® 71260) and previously involved regions every 6 months for 2 years, then annually until year 10
Thymoma, R1 or R2 resection	• CT Chest with contrast (CPT® 71260) and previously involved regions every 6 months for 2 years, then annually until year 10
Thymic carcinoma, R0 resection	• CT Chest with contrast (CPT® 71260) every 6 months for 2 years and then annually until year 5
Thymic carcinoma, R1 or R2 resection	• CT Chest with contrast (CPT® 71260) and previously involved regions every 3 months for 2 years, then annually until year 5

Evidence Discussion

Thymoma surveillance is stratified into resection categories by NCCN. Thymoma surveillance should be with CT Chest with contrast and any previously involved areas for 10 years due to the risk of late recurrence.[3] Thymic carcinoma, like thymoma, management depends on the extent of resection. NCCN stated "patients who have an R0 resection have a 5-year survival of approximately 60%".[3] Thymic carcinoma surveillance recommendations from NCCN are based on consensus as there is a paucity of published studies specifically addressing surveillance imaging of thymic carcinoma. The recommendation includes imaging for 5 years.[3]

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Breast Cancer (ONC-11)

Guideline

Breast Cancer – General Considerations (ONC-11.0)
Breast Cancer – Suspected/Diagnosis (ONC-11.1)
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Breast Cancer – Restaging/Recurrence (ONC-11.3)
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References (ONC-11)

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Breast Cancer – General Considerations (ONC-11.0)

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- This guideline applies to invasive carcinoma and ductal carcinoma in situ histologies of breast cancer.
- Advanced imaging to evaluate for distant metastases is not indicated for asymptomatic individuals with invasive carcinoma or ductal carcinoma in situ (DCIS).
- High-risk lesions, such as LCIS, ADH, and ALH are discussed in **Breast MRI Indications (BR-5.1)**.
- Bone scan has a high concordance rate with PET for detecting bone metastases.
- Scintimammography and Breast Specific Gamma Imaging (BSGI) are considered experimental, investigational, or unproven.

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Breast Cancer – Suspected/Diagnosis (ONC-11.1)

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- See: **Breast MRI Indications (BR-5.1)** in the Breast Imaging Guidelines for evaluation of suspected breast cancer.

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Breast Cancer – Initial Work-up/Staging (ONC-11.2)

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Indication	Medically Necessary Imaging Study
Newly diagnosed breast cancer or ductal carcinoma in situ	• Diagnostic bilateral mammogram and/or Ultrasound Breast (CPT® 76641 or CPT® 76642) are imaging modalities of choice • MRI Breast bilateral without and with contrast (CPT® 77049)
ANY of the following: • Atypical ductal hyperplasia (ADH) • Atypical lobular hyperplasia (ALH) • Lobular carcinoma in situ (LCIS)	See: **Breast MRI Indications (BR-5.1)**
ANY of the following: • Ductal carcinoma in situ • Stage I-III	• For sentinel lymph node evaluation: Lymph system imaging (lymphoscintigraphy, CPT® 78195) ◦ SPECT/CT (CPT® 78830) if requested
Stages I, II, and operable stage III (N1 disease)	• Routine systemic imaging is not medically necessary for initial staging of non-metastatic breast cancer in the absence of signs or symptoms

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Indication	Medically Necessary Imaging Study
ANY of the following: • Clinically suspected or biopsy-proven distant metastases/Stage IV disease (not locally advanced disease with three or less positive axillary nodes) • Signs or symptoms of systemic disease • Elevated liver function tests or tumor markers • Inflammatory breast cancer (stage T4d) • 4 or more axillary lymph nodes positive for cancer involvement (i.e., N2 disease)	ANY or ALL of the following: • CT Chest (CPT® 71260) **and** CT Abdomen and Pelvis (CPT® 74177) with contrast • Bone scan (CPT® 78306) (if PET/CT is not being performed) See: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes
ANY of the following: • Stage III N2 disease • T4 disease • Inflammatory breast cancer (stage T4d) • Inconclusive CT and/or bone scan	In addition to the above: • FDG PET/CT (CPT® 78815)
Bone pain	• Bone scan (CPT® 78306) (see: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)**) for additional bone scan codes • PET/CT (CPT® 78815) with Sodium Fluoride radiotracer if CT, MRI, Bone scan and FDG PET/CT scan are inconclusive for bone metastases • See: **Bone (Non-Vertebral) Metastases (ONC-31.5)** • See: **Spinal/Vertebral Metastases (ONC-31.6)**

Evidence Discussion

Evaluation of disease in the breast/axilla with breast MRI:

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National Comprehensive Cancer Network (NCCN) guidelines stated that breast MRI "may be used for staging evaluation to define extent of cancer or presence of multifocal or multicentric cancer in the ipsilateral breast, or to screen the contralateral breast at the time of initial diagnosis".[1] Disagreement continues to exist as to whether the benefit of breast MRI in initial staging outweighs the drawbacks. Detractors cite evidence of increased time-to-surgery, high false-positive rates among the reasons to avoid universal usage of breast MRI in initial staging.[12,32] The American Society of Breast Surgeons Consensus (ASBrS) statement recommended against the use of routine MRI in the preoperative workup of individuals with breast cancer.[11] MRI may be helpful in elucidating whether disease exists in the intervening breast tissue thereby aiding in tumor size estimation and the decision to opt for mastectomy vs. lumpectomy. NCCN cautioned that "surgical decisions should not be based solely on MRI findings".[1] Breast MRI has been shown to find occult primary cancers in roughly two thirds of patients who present with positive axillary lymph nodes, allowing for definitive surgical management.[31] NCCN stated that breast MRI "may be helpful for evaluation before and after preoperative systemic therapy to define extent of disease, response to treatment, and potential for breast-conservation therapy".[1] Breast MRI has also been shown to more accurately predict tumor size in individuals with invasive lobular carcinoma than conventional imaging.[36] While data are limited on the use of breast MRI in the setting of Paget's disease of the breast, one study found that for individuals with a histologic diagnosis of Paget's disease and a negative mammogram, MRI was able to detect occult cancer in 4/8 (50%) individuals.[34] NCCN guidelines noted that there is considerable controversy in the use of MRI based on breast density.[1] They noted that MRI advocates argue that it has a high sensitivity to find occult disease in "dense breasts where mammographically occult disease is more likely to elude preoperative detection"; however, MRI detractors note the high percentage of false- positive findings, resulting in further workup, overestimation of extent of disease and increased frequency of mastectomy. Given the recommendation by NCCN that breast MRI may be useful for specific circumstances in initial staging, these guidelines allow for the approval of breast MRI in initial staging to empower individuals and providers to discuss the risks and benefits of this modality and move forward with the most advantageous choice for the individual's specific circumstances.

Lymphatic mapping with lymphoscintigraphy and/or SPECT/CT:

Sentinel node biopsy is important in the staging of individuals with breast cancer. However, lymphoscintigraphy has limited utility in this setting.[21] In individuals with recurrent disease who have had previous axillary surgery, lymphoscintigraphy with SPECT/CT may be helpful in delineating alternate drainage pathways.[20] In individuals who have had a positive axillary node prior to neoadjuvant chemotherapy, some authors have also found the technique to be helpful in identifying the previously positive clipped node, which may not be subsequently identified as a sentinel node.[23]

Systemic staging with CT Chest, Abdomen, Pelvis, and bone scan vs. PET/CT:

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The NCCN guidelines stated to "consider additional imaging studies only in the presence of signs and symptoms of metastatic disease and for patients who are clinically high risk".[1] This is in keeping with the ACR Appropriateness Criteria which stated that systemic staging is "usually not appropriate" for all newly diagnosed clinical Stage I-IIA (early stage) breast cancer, and clinical Stage IIB-III (late stage) with ER +/HER2- breast cancer .[37] Over a third of individuals with inflammatory breast cancer will have distant metastatic disease at presentation and NCCN recommended staging studies in these individuals.[1,33]

NCCN guidelines recommended CT scan for the work up for distant metastatic disease.[1] NCCN also stated that the "routine use of FDG PET/CT is not recommended in the staging of clinical stage I, II, or operable III (T3,N1) breast cancer.[1] However, NCCN indicated that PET/CT may be performed at the same time as diagnostic CT and can be helpful as a problem-solving tool when conventional imaging is suspicious or inconclusive. It is also noted to be "helpful in identifying unsuspected regional nodal disease and/or distant metastases when used in addition to standard staging studies".[1] Bone imaging is not recommended if FDG PET/CT is already going to be performed.[1] Given the above, these guidelines allow for the selected use of concomitant PET/CT for initial staging in specific clinical circumstances.

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Breast Cancer – Restaging/Recurrence (ONC-11.3)

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- For imaging related to breast reconstruction, see: **Breast Reconstruction (BR-3.1)** in the Breast Imaging Guidelines

Indication	Medically Necessary Imaging Study
ANY of the following: • End of planned neoadjuvant chemotherapy to determine resectability • Biopsy proven local recurrence • Suspicion of recurrence with inconclusive mammogram and/or ultrasound (BIRADS 0) • Mammogram and ultrasound conflicts with physical exam	• MRI Breast Bilateral without and with contrast (CPT® 77049)
After neoadjuvant chemotherapy, if sentinel lymph node evaluation is planned	• Lymph system imaging (lymphoscintigraphy, CPT® 78195) ◦ SPECT/CT (CPT® 78830) if requested
ANY of the following: • Assessing for residual disease after surgery • Assessing response to neoadjuvant chemotherapy • After lumpectomy or mastectomy, prior to adjuvant therapy	• Neither PET nor CT are medically necessary for systemic restaging after neoadjuvant chemotherapy or after surgery

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Indication	Medically Necessary Imaging Study
• Treatment response in individuals with metastatic disease and measurable disease on imaging ◦ For individuals receiving chemotherapy, imaging is indicated after every 2 cycles ◦ For individuals receiving hormonal or endocrine therapy, imaging is indicated every 3 months	• CT Chest with contrast (CPT® 71260); and CT Abdomen and Pelvis with contrast (CPT® 74177) • Bone scan (CPT® 78306) (see also: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes) In addition to the above options, for individuals receiving systemic treatment for brain metastases: • MRI Brain without and with contrast (CPT® 70553)
ANY of the following: • Elevated LFTs • Elevated tumor markers • Signs or symptoms of recurrence • Biopsy proven recurrence	Any or all of the following: • CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast • Bone scan (CPT® 78306) (See also: **Nuclear Medicine (NM) Imaging in Oncology) (ONC-1.3)** for additional bone scan codes) For individuals with prior history of brain metastases or current signs or symptoms of brain metastases: • MRI Brain without and with contrast (CPT® 70553)
• Inconclusive CT, MRI, and/or bone scan • Treatment response assessment for bone-only metastases (excluding brain metastases) and a prior bone scan has not been performed for serial comparison	• ^{18}F-FDG PET/CT (CPT® 78815)

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Indication	Medically Necessary Imaging Study
Individuals with known or suspected bone metastases AND inconclusive bone findings on ALL of the following: • CT, MRI, bone scan, and FDG PET/CT scan	• ^{18}F Sodium Fluoride PET/CT (CPT® 78815)
To determine the ER-status of suspected/known metastatic recurrence noted on CT/bone scan **and** any one of the following: • Biopsy of metastatic site is non-diagnostic/inconclusive • Biopsy of metastatic site is risky & cannot be performed (metastatic sites in the brain, spine or near vascular structures)	• ^{18}F-FES (fluoroestradiol) PET/CT scan (CPT® 78815 or CPT® 78816)

Evidence Discussion

Evaluation of disease in the breast/axilla with breast MRI:

Breast MRI has been shown to predict extent of pathological tumor response in the breast and lymph nodes after neoadjuvant systemic therapy better than conventional imaging, although may over- or under-estimate residual tumor size.[35]

While some authors have found the use of MRI to be helpful in terms of estimating size of ipsilateral breast tumor recurrences and finding multifocal or multicentric disease[27], others have found that the addition of MRI in this context did not significantly change management and increased time to definitive therapy.[26] However, as previously noted, MRI may be a useful adjunct in situations where conventional imaging is inconclusive.

Systemic staging with CT Chest, Abdomen, Pelvis, and bone scan vs. PET/CT:

As individuals with symptoms for distant metastatic disease would have had systemic staging prior to neoadjuvant chemotherapy and/or surgery, there is no indication to repeat these until treatment is completed. However, for individuals with metastatic disease, NCCN guidelines recommended CT Chest, Abdomen, and Pelvis with contrast every 2-4 cycles of chemotherapy or every 2-6 months of endocrine therapy and bone scan is recommended every 4-6 cycles of chemotherapy or every 2-6 months of endocrine therapy. Restaging using these modalities is also advised if there is concern for progression of disease. They noted that PET/CT is not routinely indicated for restaging "because of the absence of a reproducible, validated, and widely accepted set of standards for disease activity assessment". PET is instead preferred to be reserved

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as a problem-solving tool when conventional imaging is inconclusive. Additionally, NCCN noted sodium fluoride PET/CT may be helpful to detect bone metastases where other imaging is inconclusive.[1]

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Breast Cancer – Surveillance/Follow-up (ONC-11.4)

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Indication	Medically Necessary Imaging Study
Measurable metastatic disease on maintenance therapy or being monitored off therapy	ANY or ALL of the following, every 3 months for up to 5 years after completion of active treatment: • CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast • Bone scan (CPT® 78306) (see also: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes)
• Asymptomatic non-metastatic disease • Individuals receiving post-operative adjuvant therapy	• No advanced imaging
Individuals with a personal history of breast cancer (not treated with bilateral mastectomy)	• Annual MRI Breast Bilateral without and with contrast (CPT® 77049)

Evidence Discussion

Evaluation of disease in the breast/axilla with breast MRI:

NCCN guidelines suggested that "the utility of MRI in follow-up screening of most patients with prior breast cancer is undefined", but recommend annual MRI in individuals with a personal history of breast cancer who were either younger than age 50 or who have dense breasts.[1] ACR also addressed the use of MRI breast in individuals with dense breast tissue. They did not differentiate between heterogeneously and extremely dense breasts in the recommendation. ACR considered dense breasts to be heterogeneously dense (Category C) and extremely dense (Category D).[29] As individuals with breast cancer may have residual breast tissue in the ipsilateral or contralateral breast for which certain genetic mutations may increase the risk of subsequent cancers, breast MRI would also be indicated in such individuals.[1] Individuals with a clinical lifetime risk estimated to be ≥20% lifetime risk prior to their diagnosis of breast cancer and/or who had a history of ADH or lobular neoplasia would

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have been candidates for breast cancer screening with breast MRI regardless (see BR 5.1) and therefore, would equally be eligible for this screening modality after breast cancer treatment, as long as they had not had bilateral mastectomies. Individuals who have had bilateral mastectomies have little residual tissue, and therefore, surveillance with breast imaging would be of little value. A recent meta-analysis found that the rate of occult cancer in individuals with mastectomy and the rate at which MRI detected cancer in individuals after mastectomy was well below the current BIRADS benchmark for women with genetic predispositions to cancer.[25]

Systemic surveillance with CT Chest, Abdomen, Pelvis, and bone scan vs. PET/CT:

The NCCN guidelines stated "In the absence of clinical signs and symptoms suggestive of recurrent disease, there is no indication for laboratory or imaging studies for metastases screening".[1] This is in keeping with ASCO's Choosing Wisely guideline which similarly recommended against surveillance testing with biomarkers or imaging for asymptomatic breast cancer in individuals who have been treated with curative intent.[28] Several studies have shown no benefit from routine imaging which can result in unnecessary radiation exposure and biopsies, and lead to misdiagnosis and treatment related complications.[24] A recent study also found that more intensive screening for metastasis did not result in improved survival.[22]

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Sarcomas – Bone, Soft Tissue, and GIST (ONC-12)

Guideline

Bone and Soft Tissue Sarcomas – General Considerations (ONC-12.1)
Soft Tissue Sarcomas – Initial Work-up/Staging (ONC-12.2)
Soft Tissue Sarcomas – Restaging/Recurrence (ONC-12.3)
Soft Tissue Sarcomas Surveillance/Follow-up (ONC-12.4)
Gastrointestinal Stromal Tumor (GIST) (ONC-12.5)
Bone Sarcomas – Initial Work-up/Staging (ONC-12.6)
Bone Sarcomas – Restaging/Recurrence (ONC-12.7)
Bone Sarcomas – Surveillance/Follow-up (ONC-12.8)
Benign Bone Tumors – General Considerations (ONC-12.9)
Benign Bone Tumors – Initial Work-up/Staging (ONC-12.10)
Benign Bone Tumors – Restaging/Recurrence (ONC-12.11)
Benign Bone Tumors – Surveillance/Follow-up (ONC-12.12)
References (ONC-12)

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Bone and Soft Tissue Sarcomas – General Considerations (ONC-12.1)

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- Sarcomas are tumors of mesenchymal origin, classified as high-, intermediate-, and low-grade (G) tumors (sometimes described as “spindle cell” cancers). They can arise in any bony, cartilaginous, smooth muscle, skeletal muscle, or cardiac muscle tissue.
- Malignant nerve sheath tumor cell types should be imaged as high-grade sarcoma.
- Sarcomas occur in both adult and pediatric individuals, but some are more common in one age group than the other. Unless specified below, individuals age ≥18 years old should be imaged according to this guideline section.
- Exceptions include:
  - Rhabdomyosarcoma in individuals of all ages should be imaged according to guidelines in **Rhabdomyosarcoma (RMS) (PEDONC-8.2)** in the Pediatric and Special Populations Oncology Imaging Guidelines.
  - Osteogenic sarcoma (Osteosarcoma) in individuals of all ages should be imaged according to guidelines in **Osteogenic Sarcoma (OS) (PEDONC-9.3)** in the Pediatric and Special Populations Oncology Imaging Guidelines.
  - Ewing sarcoma and Primitive Neuroectodermal Tumor in individuals of all ages should be imaged according to guidelines in **Ewing Sarcoma and Primitive Neuroectodermal Tumors (ESFT) (PEDONC-9.4)** in the Pediatric and Special Populations Oncology Imaging Guidelines.
  - Kaposi’s sarcoma in individuals of all ages should be imaged according to guidelines in **Kaposi’s Sarcoma (ONC-31.10)**.
  - See: **Uterine Cancer (ONC-22)** for imaging recommendations for uterine sarcoma.
  - Desmoplastic small round cell tumor in individuals of all ages should be imaged according to guidelines in **Non-Rhabdomyosarcoma Soft Tissue Sarcomas (NRSTS) (PEDONC-8.3)** in the Pediatric and Special Populations Oncology Imaging Guidelines.

Evidence Discussion

The choice of imaging modality is driven by the primary tumor site. Cross sectional imaging of the primary site with MRI with and without contrast or CT with contrast is recommended for best illustration of anatomic detail and vascular and nodal involvement and provides flexibility for clinician discretion for choice of modality for all sites for maximum tumor definition with consideration of minimizing radiation exposure.[1,2] CT is superior for evaluation for metastatic disease of the lung, which is supported for all individuals with a newly diagnosed malignant sarcoma. Imaging both with and without

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contrast for evaluation of metastatic disease to the lung is not supported as this exposes individuals to higher radiation doses without significant clinical benefit.

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Soft Tissue Sarcomas – Initial Work-up/ Staging (ONC-12.2)

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Indication	Medically Necessary Imaging Study
All individuals	• CT Chest with (CPT® 71260) or CT Chest without (CPT® 71250) contrast • MRI without and with contrast of involved area ◦ CT of involved area if contraindication to MRI
ANY of the following: • Angiosarcoma • Alveolar soft part sarcoma • Clear cell sarcoma • Epithelioid sarcoma • Hemangiopericytoma • Leiomyosarcoma • Liposarcoma • Retroperitoneal or intra-abdominal primary site (including pelvic primary site) • Other histologies documented to have propensity for lymphatic spread and deep-seated tumors	In addition to the above, one of the following combinations: • CT Abdomen and Pelvis with contrast (CPT® 74177) • MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast • MRI Abdomen (CPT® 74183) with and without contrast and CT Pelvis (CPT® 72193) with contrast • CT Abdomen (CPT® 74160) with contrast and MRI Pelvis (CPT® 72197) without and with contrast
ANY of the following: • Myxoid round cell liposarcoma • Angiosarcoma • Alveolar soft part sarcoma • Cardiac sarcoma • Neurologic signs or symptoms raising suspicion of CNS metastases	In addition to the above: • MRI Brain without and with contrast (CPT® 70553) • MRI Cervical/Thoracic/Lumbar Spine without and with contrast (CPT® 72156, CPT® 72157, and CPT® 72158)

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Indication	Medically Necessary Imaging Study
Leiomyosarcoma	In addition to the above: • Bone scan (CPT® 78306) (see also: **Nuclear Medicine (NM) Imaging in Oncology [ONC-1.3]** for additional bone scan codes)
ANY of the following: • Grade of tumor in doubt following biopsy • Conventional imaging suggests solitary metastasis amenable to surgical resection • Inconclusive conventional imaging • Prior to planned neoadjuvant therapy	• PET/CT (CPT® 78815 or CPT® 78816)
Desmoid Tumors	ONE of the following: • CT without contrast or with contrast of the affected body part • MRI without contrast or without and with contrast of the affected body part • Imaging of lung, lymph node, and metastatic site for these tumors is not medically necessary
Dermatofibrosarcoma Protuberans (DFSP)	ONE of the following: • CT without contrast or with contrast of the affected body part • MRI without contrast or without and with contrast of the affected body part • CT Chest with (CPT® 71260) or without (CPT® 71250) contrast for: ◦ Pulmonary symptoms ◦ Abnormal chest x-ray ◦ Sarcomatous differentiation

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Evidence Discussion

- PET/CT is supported where the grade of tumor is in doubt following biopsy or to confirm oligometastatic disease amenable to local treatment, to support treatment decision making. NCCN also supported the use of PET/CT for initial staging prior to planned neoadjuvant therapy. It is also a useful tool to follow inconclusive conventional imaging.[1]
- Different subtypes of soft tissue sarcomas have different patterns of spread; thus a histologic diagnosis is essential to determine imaging strategy.
- Abdominal and pelvic imaging is not supported for extremity, trunk or head and neck primary sites, unless documented histologies with propensity for lymphatic spread.[14] Due to the propensity of myxoid and round cell liposarcomas for leptomeningeal spread, initial evaluation of the spine with MRI is supported. MRI of the brain is supported for those with CNS signs and symptoms, and for all individuals with angiosaroma, alveolar soft part sarcomas, and cardiac sarcoma.[1]
- For desmoid tumors, disease biology and patterns of recurrence do not support metastatic disease workup, CT Chest or body areas outside of the primary site subject individuals to additional radiation and incidental finding risk.[7]
- For dermatofibrosarcoma protuberans (DFSP), CT Chest is supported for sarcomatous differentiation as noted for other sarcoma histologies above, or for pulmonary symptoms. In the absence of these features, CT exposes to risk with no statistically significant clinical benefit.[10,15]

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Soft Tissue Sarcomas – Restaging/ Recurrence (ONC-12.3)

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Indication	Medically Necessary Imaging Study
ANY of the following: • After preoperative radiotherapy • After surgical resection • After adjuvant radiotherapy	• MRI without and with contrast or CT with contrast of affected body area • Chest or lymph node imaging is not medically necessary if no abnormality on previous imaging
Baseline end of therapy evaluation	• Same studies as initial work-up
ANY of the following: • Differentiate tumor from radiation or surgical fibrosis • Determine response to neoadjuvant therapy • Confirm oligometastatic disease prior to curative intent surgical resection	• PET/CT (CPT® 78815 or CPT® 78816) ◦ If treated with radiation therapy, PET/CT no sooner than 12 weeks (3 months) post completion of radiation therapy
EITHER of the following: • Chemotherapy response for individuals with measurable disease • Individuals on neoadjuvant treatment without known lung involvement	• CT with contrast or MRI without and with contrast of affected body area every 2 cycles

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Indication	Medically Necessary Imaging Study
Unresectable or metastatic disease on chemotherapy	Every 2 cycles: • CT with contrast or MRI without and with contrast of affected body area AND • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250)
Recurrence suspected	• Repeat all imaging for initial workup of specific histology and/or primary site and other symptomatic areas
Preoperative planning prior to resection	ANY or ALL of the following: • MRI without contrast or without and with contrast of involved area • CT (contrast as requested) of involved area
Dermatofibrosarcoma Protuberans (DFSP)	• CT without contrast or with contrast of the affected body part or MRI without contrast or without and with contrast of the affected body part • CT Chest with contrast (CPT® 71260) or CT Chest without (CPT® 71250) contrast for: ◦ Known prior thoracic disease ◦ New or worsening pulmonary symptoms ◦ New or worsening chest x-ray ◦ Sarcomatous differentiation

Evidence Discussion

- Local therapy is a cornerstone of treatment for sarcomas. Cross-sectional imaging of primary site, with modality used at diagnosis specific to tumor site, is supported after pre-operative radiotherapy, and after resection of adjuvant radiotherapy to determine response, as well as for pre-operative planning prior to resection and every two cycles of treatment during active therapy. NCCN supported imaging for a baseline at the end of therapy. In the absence of known lung involvement or pulmonary symptoms, restaging of lung on active treatment does not provide benefit in most histologies and exposes individuals to additional radiation and risk of incidental findings.[1]
- NCCN indicated that PET/CT may be useful for therapy response. Individuals with baseline tumor SUVmax ≥6 and <40% decrease in FDG avidity after neoadjuvant

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therapy are at high risk for disease recurrence. Pretreatment tumor SUVmax and change in SUV max after neoadjuvant therapy has been shown to identify individuals at high risk of tumor recurrence and may be used to identify individuals most likely to benefit from additional chemotherapy.[13] PET/CT is supported to assess neoadjuvant therapy response, to differentiate scarring from disease, or to confirm oligometastatic disease prior to resection.[1,13]

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Soft Tissue Sarcomas Surveillance/ Follow-up (ONC-12.4)

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Indication	Medically Necessary Imaging Study
For any of the following: • Retroperitoneal/intra-abdominal primary site (including pelvic primary site) • Angiosarcoma • Epithelioid sarcoma	ANY or ALL of the following every 3 months for 3 years, then every 6 months for 2 more years, then annually: • CT Chest with (CPT® 71260) or without (CPT® 71250) contrast • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast or MRI without and with contrast of any other involved body areas
Myxoid/round cell liposarcoma	ANY or ALL of the following every 3 months for 2 years, then every 6 months for 2 more years, then annually: • CT Chest with (CPT® 71260) or without (CPT® 71250) contrast • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast or MRI without and with contrast of any other involved body areas • MRI Cervical/Thoracic/Lumbar Spine without and with contrast (CPT® 72156, CPT® 72157, and CPT® 72158)
Low-grade/Stage I extremity or trunk, primary site	ANY or ALL of the following every 6 months for 2 years, then annually thereafter: • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) • CT with contrast, MRI without contrast, or MRI without and with contrast of primary site

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Indication	Medically Necessary Imaging Study
ANY of the following: • Extremity/trunk primary site - grade II/stage II or higher • Head/neck primary site	ANY or ALL of the following every 3 months for 2 years, then every 6 months for 2 more years, then annually: • CT with contrast, MRI without contrast, or MRI without and with contrast of primary site • CT Chest with (CPT® 71260) or without (CPT® 71250) contrast • CT with contrast or MRI without and with contrast of any other involved body areas
ANY of the following: • Angiosarcoma • Alveolar soft part sarcoma • Cardiac sarcoma	In addition to the above studies: • MRI Brain without and with contrast (CPT® 70553) annually For surveillance of individuals with known brain metastases, see: **Brain Metastases (ONC-31.3)**
Desmoid tumors	ONE of the following every 3 months for 3 years, then every 6-12 months: • CT without contrast or with contrast of the affected body part • MRI without contrast or without and with contrast of the affected body part
Dermatofibrosarcoma Protuberans	• No routine imaging unless clinical signs/symptoms of recurrence

Evidence Discussion

Time frames, modality, and body site for surveillance by histology are based on tumor recurrence patterns specific to primary site and tumor biology. PET/CT is not supported for asymptomatic surveillance, as this can lead to unnecessary radiation exposure and invasive procedures or excess treatment.[1,7,10]

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Gastrointestinal Stromal Tumor (GIST) (ONC-12.5)

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General Considerations

- GISTs are mesenchymal neoplasms of the gastrointestinal (GI) tract, mostly found in the stomach and upper small bowel, commonly metastasizing to the liver and abdominal cavity and primarily treated with surgery.
- Recurrence risk of GIST is estimated by prognostic model based on location, size of primary tumor, and mitotic rate per high power field (HPF).
- High-risk category includes any tumor >5 cm with >5 mitoses/50 HPF and any tumors >10 cm in size regardless of mitotic rate.

Indication	Medically Necessary Imaging Study
Suspected/Diagnosis	• CT Abdomen and Pelvis with contrast (CPT® 74177)
Initial Work-up/Staging	• CT Chest (CPT® 71260) with contrast or CT Chest without contrast (71250) and • CT Abdomen and Pelvis (CPT® 74177) with contrast, if not already performed
In addition to the above imaging for initial staging of either of the following: • Liver lesions noted on initial CT • Preoperative assessment of liver	• MRI Abdomen without and with contrast (CPT® 74183)
Monitoring response to treatment (every 8 to 12 weeks) in any of the following: • Unresectable primary disease • Metastatic disease • Resectable disease with significant morbidity	EITHER of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)

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Indication	Medically Necessary Imaging Study
Additional treatment response, in addition to the above imaging, for known or suspected chest involvement	• CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250)
Evaluation of inconclusive findings on conventional imaging	• PET/CT (CPT® 78815)
Surveillance for any of the following: • Incompletely resected • Metastatic disease • High-risk disease	Every 3 months for 5 years, then annually: • CT Abdomen and Pelvis with contrast (CPT® 74177)
Surveillance for completely resected, low-risk disease	Every 6 months for 5 years, then annually: • CT Abdomen and Pelvis with contrast (CPT® 74177)
Known or suspected recurrence	ANY or ALL of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197) for known or suspected liver involvement • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) for known or suspected chest involvement

Evidence Discussion

Suspected/Diagnosis and Initial Staging

CT Abdomen and Pelvis are recommended by NCCN for suspected GIST.[3]

NCCN stated that CT is the "imaging modality of choice to characterize an abdominal mass, as well as to evaluate its extent and the presence or absence of metastasis at the initial staging workup".[3] While CT Chest is supported to rule out metastatic disease in biopsy-proven GIST, advanced imaging prior to confirmation of diagnosis may expose individuals to unnecessary radiation and increased irrelevant incidental findings. MRI is an adjunct to CT to provide anatomical definition of liver metastases.[3] NCCN noted that PET/CT is not a substitute for diagnostic CT, which has superior sensitivity for this tumor

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site, but PET/CT is supported for inconclusive CT findings as it can "help differentiate tumor from necrotic or inactive scar tissue, malignant from benign tissue, and recurrent tumor from nondescript benign changes".[3].

Restaging

Abdominal/pelvic imaging every 8-12 weeks to assess response to TKI is appropriate given the typical response timeframe for this treatment.[17] NCCN stated "since there is a 95% correlation between the information from regular contrast-enhanced CT and PET/CT, CT with IV contrast is the preferred routine imaging modality for patients with GIST on TKI therapy".[3] More frequent imaging may lead to premature or incorrect treatment decisions. Chest imaging in the absence of prior chest findings or signs and symptoms of chest involvement is low-yield and not recommended by NCCN, it poses potential for risk of increased incidental findings and increased radiation exposure.[3]

Surveillance

Surveillance guidance from NCCN stated that imaging should be performed every three to six months for five years. More frequent surveillance imaging is recommended by NCCN for high-risk tumors. Less frequent imaging is acceptable for low-risk tumors.[3]

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Bone Sarcomas – Initial Work-up/Staging (ONC-12.6)

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- Osteogenic sarcoma (Osteosarcoma) in individuals of all ages should be imaged according to guidelines in **Osteogenic Sarcoma (OS) (PEDONC-9.3)** in the Pediatric and Special Populations Oncology Imaging Guidelines.
- Ewing sarcoma and Primitive Neuroectodermal Tumor in individuals of all ages should be imaged according to guidelines in **Ewing Sarcoma and Primitive Neuroectodermal Tumors (ESFT) (PEDONC-9.4)** in the Pediatric and Special Populations Oncology Imaging Guidelines.

Indication	Medically Necessary Imaging Study
Chondrosarcoma • Low-grade intra-compartmental • High-grade (grade II or grade III) • Clear cell • Extra-compartmental	ANY or ALL of the following: • MRI without contrast or without and with contrast of involved area • CT (contrast as requested) of involved area • CT Chest with (CPT® 71260) or without (CPT® 71250) contrast
Dedifferentiated chondrosarcoma	See: **Osteogenic Sarcoma (OS) (PEDONC-9.3)** for imaging
Mesenchymal chondrosarcoma	See: **Ewing's Sarcoma Family of Tumors (PEDONC-9.4)** for imaging

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Indication	Medically Necessary Imaging Study
Chordoma	ANY or ALL of the following: • MRI without contrast or without and with contrast of involved area • CT (contrast as requested) of involved area • CT Chest with (CPT® 71260) or without (CPT® 71250) contrast • CT Abdomen and Pelvis with contrast (CPT® 74177) • MRI Cervical (CPT® 72156), Thoracic (CPT® 72157), and Lumbar (CPT® 72158) Spine without and with contrast • Bone scan (CPT® 78306) (see also: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes)
Chordoma with inconclusive findings on conventional imaging	PET/CT (CPT® 78815 or CPT® 78816)

Evidence Discussion

The choice of imaging modality is driven by the primary tumor site. Cross-sectional imaging of the primary site with MRI with and without contrast or CT with contrast is recommended for best illustration of anatomic detail and vascular and nodal involvement. Our guideline provides flexibility for provider discretion for choice of modality for all sites. Providers should choose modality expected to offer maximum primary tumor definition with consideration of minimizing radiation exposure.[2] CT is more sensitive and specific than MRI for evaluation for metastatic disease of the lung and is supported for all individuals with a newly diagnosed malignant sarcoma. Imaging both with and without contrast for evaluation of metastatic disease to the lung is not supported as this exposes individuals to higher radiation doses without significant clinical benefit. CT either with or without contrast should be selected at discretion of the provider.

Chordomas have a propensity for the distant disease at presentation including spine, so unlike other bone sarcomas, imaging of the abdomen and pelvis with contrasted CT as well as bone scan and MRI of the spine are supported. FDG PET/CT is supported only for inconclusive conventional imaging. PET is not generally supported for initial staging of other histologies discussed in this section due to low sensitivity and specificity.[2]

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Bone Sarcomas – Restaging/Recurrence (ONC-12.7)

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Indication	Medically Necessary Imaging Study
Chondrosarcoma • Low-grade intra-compartmental • High-grade (grade II or grade III) • Clear cell • Extra-compartmental	ANY or ALL of the following, after completion of radiotherapy or every 2 cycles of chemotherapy: • MRI without contrast or without and with contrast of involved area • CT (contrast as requested) of involved area • CT Chest with (CPT® 71260) or without (CPT® 71250) contrast
Suspected recurrence of atypical cartilaginous tumor (low-grade intra-compartmental appendicular tumor)	• MRI without contrast or without and with contrast of involved area or CT (contrast as requested) of involved area • CT Chest with (CPT® 71260) or without (CPT® 71250) contrast • Bone scan (CPT® 78306) (see also: **Nuclear Medicine (NM) Imaging in Oncology [ONC-1.3]** for additional bone scan codes)
Dedifferentiated chondrosarcoma	See: **Osteogenic Sarcoma (OS) (PEDONC-9.3)** for imaging recommendations
Mesenchymal chondrosarcoma	See: **Ewing's Sarcoma Family of Tumors (PEDONC-9.4)** for imaging recommendations
Chordoma	ANY or ALL of the following, after completion of radiotherapy or every 2 cycles of chemotherapy: • MRI without contrast or without and with contrast of involved area • CT (contrast as requested) of involved area • Bone scan (CPT® 78306) (see also: **Nuclear Medicine (NM) Imaging in Oncology [ONC-1.3]** for additional bone scan codes)

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Indication	Medically Necessary Imaging Study
Chordoma with inconclusive findings on conventional imaging	PET/CT (CPT® 78815 or CPT® 78816)

Evidence Discussion

CT Chest is supported for restaging for all bone sarcomas, as well as MRI of primary site. CT of other body areas is driven by clinical symptoms and patterns of spread at primary site and not routine across all cell types .[2] PET/CT for restaging is not routinely supported but may be used for inconclusive conventional imaging.[2]

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Bone Sarcomas – Surveillance/Follow-up (ONC-12.8)

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Indication	Medically Necessary Imaging Study
• Intra-compartmental Chondrosarcoma	ANY or ALL of the following every 6-12 months for 2 years, then annually for 10 years: • Plain x-ray of primary site ◦ MRI without and with contrast for new findings on plain x-ray or new/worsening clinical symptoms. • Chest x-ray ◦ CT Chest with (CPT® 71260) or without (CPT® 71250) contrast for new findings on chest x-ray, or new/worsening signs/symptoms
• Grade I, II, or III Chondrosarcoma • Clear Cell Chondrosarcoma • Extra-compartmental Chondrosarcoma • Low-grade extra-compartmental appendicular tumors	ANY or ALL of the following every 6 months for 5 years, then annually for 10 years: • Plain x-ray of primary site ◦ MRI without and with contrast for new findings on plain x-ray or new/worsening clinical symptoms. • CT Chest with (CPT® 71260) **or** CT Chest without (CPT® 71250) contrast
Dedifferentiated chondrosarcoma	See: **Osteogenic Sarcoma (OS) (PEDONC-9.3)** for imaging recommendations
Mesenchymal chondrosarcoma	See: **Ewing's Sarcoma Family of Tumors (PEDONC-9.4)** for imaging recommendations

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Indication	Medically Necessary Imaging Study
Chordoma	• Plain x-ray of primary site every 6 months for 5 years and then annually until year 10 ◦ MRI without and with contrast for new findings on plain x-ray or new/worsening clinical symptoms. • Chest x-ray every 6 months for 5 years and then annually until year 10 ◦ CT Chest with (CPT® 71260) or without (CPT® 71250) contrast annually or for evaluation of any new findings on chest x-ray or new/worsening signs/symptoms

Evidence Discussion

Data do not show an overall survival benefit with advanced imaging surveillance of sarcomas. Less than 20% of local recurrences are detected based on advanced imaging surveillance in asymptomatic individuals. Sensitivity and specificity of chest imaging are higher in grade two or higher disease.[18]

For grades I-III disease, plain x-ray is supported as primary tool for primary site surveillance, with cross sectional advanced imaging for signs and symptoms of progression or changes on x-ray. Chest imaging is supported with either plain imaging or CT. Recurrence beyond 10 years is rare; asymptomatic surveillance imaging beyond 10 years is low yield and is not generally supported.[2]

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Benign Bone Tumors – General Considerations (ONC-12.9)

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- Variety of diagnoses, including osteoid osteochondroma, chondroblastoma, desmoplastic fibroma, Paget's disease, osteoid osteoma, and others.
- Plain x-ray appearance is diagnostic for many benign bone tumors and advanced imaging is generally not medically necessary except for preoperative planning.
- MRI without and with contrast is the primary modality for advanced imaging of bone tumors and is medically necessary to help narrow differential diagnoses and determine whether biopsy is indicated.
- Some benign bone tumor types carry a risk of malignant degeneration over time, but routine advanced imaging surveillance has not been shown to improve outcomes for these individuals.
- MRI without and with contrast can be approved to evaluate new findings on plain x-ray new/worsening clinical symptoms not explained by a recent plain x-ray.
- There are no data to support the use of PET/CT in the evaluation of benign bone tumors, and PET requests are not medically necessary without biopsy confirmation of a malignancy.
- Other benign bone tumors should be imaged according to guidelines in **Bone Lesion (MS-10.2)** in the General Musculoskeletal Imaging Guidelines or **Mass Involving Bone (including Lytic and Blastic Metastatic Disease) (PEDMS-3.4)** in the Pediatric Musculoskeletal Imaging Guidelines.

Evidence Discussion

Many benign bone tumors have characteristic appearance on plain x-ray, particularly in conjunction with history, individual age, and size and growth characteristics. Lesions without aggressive appearing characteristics on x-ray generally do not require further evaluation. Advanced imaging modalities are supported when x-ray is indeterminate for malignancy to determine management strategy. Thus, the advanced imaging guidelines in this section pertain to enchondromas, which often appear indeterminate on plain x-ray, and giant cell tumor of bone (GCTB), which have potential for malignant degeneration and metastasis.[2,19]

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Benign Bone Tumors – Initial Work-up/ Staging (ONC-12.10)

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Indication	Medically Necessary Imaging Study
Giant Cell Tumor of Bone (GCTB)	ANY or ALL of the following: • MRI without contrast or without and with contrast of involved area • CT (contrast as requested) of involved area • CT Chest with (CPT® 71260) or without (CPT® 71250) contrast • Bone scan (CPT® 78306) (see also: **Nuclear Medicine (NM) in Oncology [ONC-1.3]** for additional bone scan codes)
Enchondroma	• MRI without contrast or without and with contrast of primary site

Evidence Discussion

- Giant Cell Tumor of Bone
  - MRI can help distinguish malignant transformation, while complex bony anatomy maybe better visualized on CT. To establish management strategy, our guidelines support using both modalities for involved areas in alignment with NCCN and ACR.[2,16]
  - CT Chest and whole-body bone scan are supported at time of initial staging given the malignant and metastatic potential of GCTB. CT Abdomen and Pelvis are not supported without symptoms in these areas as this would not be a typical pattern of metastasis in the setting of malignant degeneration of GCTB. CT of abdomen and pelvis increases radiation exposure with low yield.[2]
- Enchondroma
  - MRI can help distinguish suspected enchondroma on plain film from other more malignant entities and is supported for initial staging to confirm characteristic appearance.[19]

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Benign Bone Tumors – Restaging/ Recurrence (ONC-12.11)

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Indication	Medically Necessary Imaging Study
Giant Cell Tumor of Bone (GCTB)	ANY or ALL of the following, after completion of radiotherapy or every 2 cycles of chemotherapy: • MRI without contrast or without and with contrast of involved area • CT (contrast as requested) of involved area • Bone scan (CPT® 78306 (see also: **Nuclear Medicine (NM) Imaging in Oncology [ONC-1.3]** for additional bone scan codes)
Enchondroma	Plain films of primary site

Evidence Discussion

- GCTB
  - For individuals requiring chemotherapy, repeat of all imaging done at initial staging may be done every two cycles to assess treatment response or need to change therapy. For individuals treated with radiotherapy, repeat imaging may be done at completion of radiotherapy to verify treatment response and establish baseline for surveillance.[2,16]
- Enchondroma
  - Once initial staging with advanced imaging has been completed, plain films should be adequate to ensure stability or for suspected recurrence, restaging after local therapy, or surveillance. Further advanced imaging is generally low yield unless there are indeterminate findings on the plain films.[19]

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Benign Bone Tumors – Surveillance/ Follow-up (ONC-12.12)

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Indication	Medically Necessary Imaging Study
Giant Cell Tumor of Bone (GCTB)	ANY or ALL of the following every 6-12 months for 4 years, then annually thereafter: • Plain x-ray of primary site ◦ MRI without and with contrast is indicated for new findings on plain x-ray or new/worsening clinical symptoms. • Chest x-ray ◦ CT Chest with (CPT® 71260) or without (CPT® 71250) contrast for new findings on chest x-ray, or new/worsening signs/ symptoms.
Enchondroma	Plain films of primary site

Evidence Discussion

- GCTB
  - The role of advanced imaging in asymptomatic surveillance is not well established for GCTB. Though late recurrences can occur, there is not strong data to support advanced imaging over plain film in asymptomatic individuals. These guidelines allow advanced imaging if there are indeterminate findings on plain film, both for primary site and chest. Time frames for plain films are in alignment with NCCN. [2,16]
- Enchondroma
  - Once initial staging with advanced imaging has been completed, plain films should be adequate to ensure stability or further imaging for recurrence, restaging after local therapy, or surveillance . Further advanced imaging is generally low yield unless there are indeterminate findings on the plain films.[19]

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Pancreatic Cancer (ONC-13)

Guideline

Pancreatic Cancer – General Considerations (ONC-13.0)
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Pancreatic Cancer – General Considerations (ONC-13.0)

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- This guideline refers only to adenocarcinoma of the exocrine pancreas, which accounts for over 90% of pancreatic malignancies. This guideline may also be used for cancer of the Ampulla of Vater.
- Neuroendocrine and carcinoid tumors of the pancreas are not included in this guideline, see: **Neuroendocrine Cancers and Adrenal Tumors (ONC-15)**.

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Pancreatic Cancer – Screening Studies for Pancreatic Cancer (ONC-13.1)

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- Detailed history of any known inherited syndrome in the individual and detailed family history in first- and second-degree relatives, including the age and lineage, is essential to guide screening recommendations. See table below for age- and risk-specific screening recommendations.
- New onset of diabetes in individuals older than 50 has been recognized as a potential indicator of the development of pancreatic cancer. Approximately 1% of individuals in this category are diagnosed with cancer within 3 years. A prediction model has been established which identifies those individuals at greatest risk for pancreatic malignancy. The scoring system, known as ENDPAC (Enriching New-Onset Diabetes for Pancreatic Cancer) is based on 3 discriminatory factors, including change in blood glucose, change in weight, and age of onset at the time of the new diagnosis of diabetes. A score of >3 imparts an elevated risk of pancreatic cancer (3.6%), and these individuals should be screened. Screening is not medically necessary at this time for scores of 0-2.

Indications	Medically Necessary Imaging Study
Individuals who meet **BOTH** of the following criteria: • One or more first- or second-degree relative affected with pancreatic cancer **AND** • Known mutation carrier of ONE of the following genes: ◦ Lynch Syndrome (MLH1, MSH2, or MSH6 gene mutations) ◦ BRCA1 ◦ PALB2 mutation ◦ EPCAM ◦ TP53	• MRI Abdomen without and with contrast (CPT® 74183) or MRCP with 3D rendering (CPT® 74183 and CPT® 76376 or CPT® 76377) starting at age 50 or 10 years earlier than the youngest family member affected with exocrine pancreatic cancer, repeat annually

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Indications	Medically Necessary Imaging Study
Individuals with family history of pancreatic cancer but no known genetic mutation: • Individuals with 2 relatives with pancreatic cancer where one is a first-degree relative • Individuals with 3 or more relatives with pancreatic cancer	• MRI Abdomen without and with contrast (CPT® 74183) or MRCP with 3D rendering (CPT® 74183 and CPT® 76376 or CPT® 76377) starting at age 45 or 10 years earlier than the youngest family member affected with exocrine pancreatic cancer, repeat annually
Pancreatic Cancer Kindred (individuals who have at least one first-degree relative with pancreatic cancer who in turn also has a first-degree relative with pancreatic cancer) and NO known genetic germline mutations	• MRI Abdomen without and with contrast (CPT® 74183) or MRCP with 3D rendering (CPT® 74183 and CPT® 76376 or CPT® 76377) starting at age 50 or 10 years earlier than the youngest family member affected with exocrine pancreatic cancer, repeat annually
Hereditary Pancreatitis (PRSS1, CPA1, and CTRC gene mutations)	• MRI Abdomen without and with contrast (CPT® 74183) or MRCP with 3D rendering (CPT® 74183 and CPT® 76376 or CPT® 76377) beginning at age 40 or 20 years after the first pancreatitis attack, repeat annually.
Peutz-Jeghers Syndrome (LKB1/STK11 gene mutation)	• MRI Abdomen without and with contrast (CPT® 74183) or MRCP with 3D rendering (CPT® 74183 and CPT® 76376 or CPT® 76377) starting at age 30 or 10 years earlier than the youngest family member affected with exocrine pancreatic cancer, repeat annually ◦ Family history is not required to begin imaging at age 30

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Indications	Medically Necessary Imaging Study
CDKN2A mutation (also known as p16, p16INK4a, and MTS1, FAMM-Familial Atypical Multiple Melanoma and Mole Syndrome)	• MRI Abdomen without and with contrast (CPT® 74183) or MRCP with 3D rendering (CPT® 74183 and CPT® 76376 or CPT® 76377) beginning at age 40 or 10 years earlier than the youngest family member affected with exocrine pancreatic cancer, repeat annually. ◦ Family history is not required to begin imaging at age 40
• BRCA2 • ATM (Ataxia-Telangiectasia)	• MRI Abdomen without and with contrast (CPT® 74183) or MRCP with 3D rendering (CPT® 74183 and CPT® 76376 or CPT® 76377) starting at age 50 or 10 years earlier than the youngest family member affected with exocrine pancreatic cancer, repeat annually. ◦ Family history is not required to begin imaging at age 50
Screening MRI reveals cystic lesion of the pancreas	• Repeat MRI Abdomen without and with contrast (CPT® 74183) or MRCP with 3D rendering (CPT® 74183 and CPT® 76376 or CPT® 76377) in 6 months
Screening MRI reveals indeterminate solid lesion	• CT Abdomen with contrast – pancreatic protocol (CPT® 74160) • Repeat MRI Abdomen without and with contrast (CPT® 74183) or MRCP with 3D rendering (CPT® 74183 and CPT® 76376 or CPT® 76377) in 3 months after the CT scan
Screening MRI reveals pancreatic stricture and/or dilation ≥6 mm without a mass	• CT Abdomen with contrast – pancreatic protocol (CPT® 74160) • Repeat MRI Abdomen without and with contrast (CPT® 74183) or MRCP with 3D rendering (CPT® 74183 and CPT® 76376 or CPT® 76377) in 3 months after the CT scan

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Indications	Medically Necessary Imaging Study
New onset diabetes in adults with ENDPAC score of ≥3	• CT Abdomen without and with contrast (CPT® 74170) or MRI Abdomen without and with contrast (CPT® 74183) or MRCP with 3D rendering (CPT® 74183 and CPT® 76376 or CPT® 76377) at baseline; if negative, repeat once after 6 months

Background and Supporting Information

ENDPAC scoring:

Blood Glucose (BG) Categories		Change BG Category Score (NOD-1y)(A)
BG Range (mg/dl)	Score	Score Range
BG Category at -1 years		1-4
<100	1	
100-109	2	
110-125	3	
BG Category at Glycemically-Defined New-Onset Diabetes		
126-160	4	
>160	5	
Change Weight Categories		Change Weight Score (B)
Change Weight (kg)	Score	Score Range
≤-6.0	+6	-6 to +6
-5.9 to -4.0	+4	
-3.9 to -2.0	+2	
-1.9 to +1.9	0	
+2.0 to +3.9	-2	
+4.0 to +5.9	-4	
≥+6.0	-6	
Age (years) at glycemically-defined new-onset diabetes		Age Score (C)

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Blood Glucose (BG) Categories		Change BG Category Score (NOD-1y)(A)
Age Range	Score	Score Range
≤59	-1	-1 to +1
60 to 69	0	
≥70	+1	
Total Score		A + B + C

Evidence Discussion

International Cancer of the Pancreas Screening Consortium (CAPS) recommended screening for those with an estimated lifetime risk of pancreatic cancer >5% to facilitate early detection, as the survival of individuals diagnosed with advanced disease at presentation is extremely poor. Individuals may be high-risk due to family history of 2-3 relatives with pancreatic adenocarcinoma with first degree relative affected, or those with known deleterious genetic mutations in conjunction with one first- or second-degree relative with pancreatic adenocarcinoma.[3,14,17] Asymptomatic screening has not been shown to improve outcomes in those without an established lifetime risk of >5%, including those with only more distant relatives affected, a single relative affected and no known high-risk mutation, or those with mutations whose risk is unknown.[3,14]

The lifetime risk and age at presentation varies with each genetic mutation. Updated CAPS recommendations generally support imaging at age 50 or ten years younger than the age of the youngest relative with pancreatic adenocarcinoma. These guidelines align with CAPS and NCCN with multiple exceptions to this to allow screening at younger ages for individuals with mutations known to be higher risk or present at younger ages.[17,13] US Preventative Services Task Force (USPSTF) did not generally recommend pancreatic cancer screening, though they did not evaluate individuals with high-risk criteria in this data. The USPSTF noted that screening has moderate risk due to unnecessary imaging and management of incidental findings.[4] These findings further support that screening for those that do not meet the clearly defined risk factors listed in the guideline is not indicated.

MRI without and with contrast shows up to 93% sensitivity for pancreatic lesions and better illustrates pancreatic ducts, which may indirectly identify pancreatic malignancy, and is the preferred modality for screening for most individuals in these guidelines. This is superior to both CT and endoscopic ultrasound, which may not detect smaller lesions.[15] CT pancreatic protocol is supported in these guidelines if indeterminate findings on MRI in the interest of early detection.

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A unique group is individuals with new onset diabetes and ENDPAC score >3. These individuals are at an elevated risk of developing pancreatic cancer within 6 months even in the absence of family history or known deleterious mutations. MRI or CT is supported in this population at diagnosis of diabetes and again in 6 months.[16,12]

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Pancreatic Cancer – Suspected/ Diagnosis (ONC-13.2)

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Indication	Medically Necessary Imaging Study
For any suspected symptoms only (e.g., epigastric pain, weight loss, pain radiating to back, etc.)	• Ultrasound (CPT® 76700 or CPT® 76705) • Also see: **Epigastric Pain and Dyspepsia (AB-2.5)**
Symptoms suspicious for pancreatic cancer AND any one of the following: • Abnormal labs (e.g., elevated CA 19-9, ALKP, bilirubin, or GGTP) • Abnormal physical exam findings (e.g., abdominal mass) • Abnormal or non-diagnostic ultrasound/ERCP	Any ONE of the following: • CT Pancreatic Protocol (CT Abdomen with contrast with dual phase imaging, CPT® 74160) • MRI Abdomen without and with contrast (CPT® 74183) or MRCP with 3D rendering (CPT® 74183 and CPT® 76376 or CPT® 76377)
Preoperative studies for potentially resectable tumors without confirmed histologic diagnosis	• See: **Pancreatic Cancer – Initial Work-up/ Staging (ONC-13.3)**

Evidence Discussion

For individuals with symptoms suspicious for pancreatic cancer with abnormal labs and physical findings or abnormal or non-diagnostic ultrasound or ERCP, CT pancreatic protocol (abdomen without and with contrast) or MRI abdomen without and with contrast are supported. CT pancreatic protocol has a sensitivity and specific or 90 and 87 percent respectively.[20,19] Sensitivity and specificity of MRI and 89 and 90% respectively.[20,19] CT has the advantage of being less costly, more accessible, and faster, but exposes to more radiation. MRI may be more sensitive for visualization of pancreatic ducts and has less radiation exposure, but can be less accessible, more costly, takes longer, and can pose difficulties with claustrophobia and has more contraindications.[19] Given their similar sensitivity and specificity, these guidelines allow flexibility for individuals and providers to weigh risks and benefits for each individual for suspected disease.

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Pancreatic Cancer – Initial Work-up/ Staging (ONC-13.3)

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Indication	Medically Necessary Imaging Study
All individuals	• CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with (CPT® 74177) or CT Abdomen and Pelvis without and with contrast (CPT® 74178)
For any of the following: • Preoperative planning • CT insufficient to determine resectability • Evaluation of indeterminate liver lesions	• MRI Abdomen without and with contrast (CPT® 74183) or MRCP with 3D rendering (CPT® 74183 and CPT® 76376 or CPT® 76377)
No evidence of metastatic disease on CT or MRI AND any of the following: • Equivocal or indeterminate conventional imaging findings • Markedly elevated CA 19-9 • Large primary tumor(s) • Enlarged regional lymph nodes • Planned neoadjuvant therapy	• PET/CT (CPT® 78815)

Evidence Discussion

For biopsy proven pancreatic adenocarcinoma, evaluation for metastatic disease with contrasted CTs of the chest, abdomen and pelvis are supported, given that approximately 80% of individuals have metastatic or locally advanced disease at presentation.[20] Resectability has a dramatic impact on prognosis, and MRI abdomen with and without contrast is supported in addition to CT if CT insufficient to determine resectability, for preoperative planning, or to evaluate indeterminate liver lesions.[1] Given the high incidence of metastatic disease at presentation, if high-risk features are noted but no metastatic disease is visible on conventional imaging, a PET/CT is

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supported to assess for occult extra-pancreatic metastatic disease, in alignment with the NCCN. This is not a substitute for a diagnostic-quality contrasted CT or MRI, which is superior for detecting pancreatic disease.[1,19] PET/MRI has a weak expert consensus without sufficient data, and as such these guidelines do not routinely support this modality.[1,21,22,24]

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Pancreatic Cancer – Restaging/ Recurrence (ONC-13.4)

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Indication	Medically Necessary Imaging Study
For ANY of the following: • After neoadjuvant therapy • Post-operative baseline • Suspected recurrence	• CT Chest with contrast (CPT® 71260) • Abdominal imaging with one of the following, using same modality as used at initial evaluation: ◦ CT Abdomen and Pelvis with (CPT® 74177) ◦ CT Abdomen and Pelvis without and with contrast (CPT® 74178) ◦ MRI Abdomen without and with contrast (CPT® 74183) ◦ MRCP with 3D rendering (CPT® 74183 and CPT® 76376 or CPT® 76377) • CT with contrast of other involved or symptomatic areas
Unresectable disease or metastatic disease on chemotherapy	Every 2 cycles of treatment (commonly every 6 to 8 weeks): • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with (CPT® 74177) or CT Abdomen and Pelvis without and with contrast (CPT® 74178) • CT with contrast of other involved or symptomatic areas
Unexplained elevated liver enzymes or inconclusive recent CT abnormality	• MRI Abdomen without and with contrast (CPT® 74183) or MRCP with 3D rendering (CPT® 74183 and CPT® 76376 or CPT® 76377)
If complete surgical resection was initial therapy	• See: **Pancreatic Cancer – Surveillance/Follow-up for surveillance imaging (ONC-13.5)**
Inconclusive findings on conventional imaging	• PET/CT (CPT® 78815)

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Evidence Discussion

For individuals with unresectable or metastatic disease on chemotherapy, imaging of the chest, abdomen and pelvis with contrast (or without and with contrast for the abdomen and pelvis) are supported every 2 cycles of treatment, given the high rate of progression and metastases, to allow for prompt consideration of changes in treatment. CT of any involved or symptomatic area is also supported. The same imaging is supported after neoadjuvant chemoradiation to assess resectability and rule out metastatic disease. Resection is the mainstay of curative therapy in pancreatic cancer, but only 20% of individuals achieve this status. Individuals with unresectable or metastatic disease are unlikely to benefit from surgery, thus pre-operative evaluation for metastasis is essential to minimize unnecessary surgical risk.[20,1] As noted in the initial staging section, both CT and MRI have advantages and disadvantages. MRI is more specific for liver disease and offers better soft tissue differentiation for inconclusive findings.[1,24] The same imaging guidance applies to suspected recurrence of disease. Restaging studies are also supported as a post-operative baseline, to ensure the absence of residual disease and make decisions regarding adjuvant treatment, and to ensure accurate comparison for surveillance imaging.

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Pancreatic Cancer – Surveillance/Follow-up (ONC-13.5)

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Indication	Medically Necessary Imaging Study
All individuals (other than resected ampullary cancer)	Every 3 months for 2 years, then annually: • CT Chest with contrast (CPT® 71260) And ANY ONE of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)
Resected ampullary cancer	Every 3 months for 2 years, then every 6 months for up to 5 years: • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) • CT Abdomen and Pelvis with contrast (CPT® 74177) or MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)
Measurable metastatic disease on maintenance therapy or being monitored off therapy	Every 3 months for up to 5 years after completion of definitive treatment, then annually: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) or MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)

Evidence Discussion

Data on the role of surveillance in pancreatic cancer are limited, due to the poor prognosis and small numbers of individuals with long-term follow up. The NCCN recommendations for surveillance are based on consensus rather than data, and SEER-Medicare data shows no significant survival benefit for individuals who received regular surveillance scans/no improved outcome with earlier detection of recurrence.[1,23] The role of ongoing imaging in individuals with metastatic disease on maintenance or observation is also unclear. There is no clear data on length of time for maintenance

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therapy in those with metastatic disease, and treatment 'holidays' are often interjected in therapy. Outside of situations where there is a clear impact on management decisions, ASCO stated that imaging should be supplanted by clinical evaluation.[24] However, the NCCN offered several second and third-line treatment options. These guidelines provide some flexibility for patient-centricity and provider preference in this setting, allowing for CT Chest, Abdomen and Pelvis every 3 months for up to 5 years and then annually after completion of definitive treatment.[1] Specifically for individuals with resected ampullary cancer, NCCN recommended surveillance after adjuvant therapy every three to six months for two years, then every six to 12 months for up to five years. Imaging studies as well as history, physical exam, and tumor marker studies are recommended components of surveillance for these individuals.[25]

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Upper GI Cancers (ONC-14)

Guideline

Hepatocellular Carcinoma (HCC) – General Considerations (ONC-14.1)
Hepatocellular Carcinoma (HCC) – Suspected/Diagnosis (ONC-14.2)
Hepatocellular Carcinoma (HCC) – Initial Work-up/Staging (ONC-14.3)
Hepatocellular Carcinoma (HCC) – Restaging/Recurrence (ONC-14.4)
Hepatocellular Carcinoma (HCC) – Surveillance/Follow-up (ONC-14.5)
Gallbladder and Biliary Tumors – Initial Work-up/Staging (ONC-14.6)
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Gastric Cancer – Initial Work-up/Staging (ONC-14.9)
Gastric Cancer – Restaging/Recurrence (ONC-14.10)
Gastric Cancer – Surveillance/Follow-up (ONC-14.11)
References (ONC-14)

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Hepatocellular Carcinoma (HCC) – General Considerations (ONC-14.1)

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- A biopsy is not always required for the diagnosis of Hepatocellular carcinoma (HCC). A dedicated triple-phase CT or MRI may be obtained. MRI with contrast is the test of choice for the evaluation of liver masses. It offers soft tissue contrast resolution superior to CT as well as the possibility of using two different contrast agents, one of which if more blood flow based and the other which also is blood flow based and demonstrates hepatobiliary function (Eovist). Classical imaging findings include:
  - arterial phase hyper-enhancement
  - venous phase washout appearance
  - capsule appearance
  - threshold growth
- For individuals who are high-risk for developing HCC (cirrhosis, chronic Hepatitis B or current or prior HCC), if the liver lesion is >1 cm with 2 classic enhancements on triple-phase CT or MRI, the diagnosis is confirmatory and biopsy is not needed.
- For lesions less than 1 cm or with less than 2 classical enhancements or for any liver lesions in individuals who are not high-risk, a biopsy is needed for histological confirmation. PET/CT scan is considered not medically necessary for the diagnosis or staging of HCC.

Evidence Discussion

HCC does not necessarily require a biopsy for diagnosis as a triple phase CT or MRI can support the diagnosis in the absence of biopsy as these lesions are characterized by arterial hypervascularity and "wash out" on portal venous phases unlike the surrounding liver. For individuals who are high-risk for developing HCC (cirrhosis, chronic Hepatitis B or current or prior HCC), if the liver lesion is >1 cm with 2 classic enhancements on triple-phase CT or MRI, the diagnosis is confirmatory and biopsy is not needed. For lesions less than 1 cm or with less than 2 classical enhancements or for any liver lesions in individuals who are not high-risk, a biopsy may be needed for histological confirmation. Serum biomarkers such as AFP are not sensitive or specific enough to establish a diagnosis. PET/CT scan is not medically necessary for the diagnosis or staging of HCC due to limited sensitivity.[2,15]

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Hepatocellular Carcinoma (HCC) – Suspected/Diagnosis (ONC-14.2)

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- See: **Chronic Liver Disease, Cirrhosis and Screening for HCC (AB-26.1)** in the Abdomen Imaging Guidelines.
- See: **Liver Lesion Characterization (AB-29.1)** in the Abdomen Imaging Guidelines.

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Hepatocellular Carcinoma (HCC) – Initial Work-up/Staging (ONC-14.3)

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Indication	Medically Necessary Imaging Study
All individuals	• CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) And ONE of the following: • CT Abdomen with contrast (CPT® 74160) • CT Abdomen without and with contrast (CPT® 74170) • CT Abdomen and Pelvis with contrast (CPT® 74177) or without and with contrast (CPT® 74178) • MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast • Bone scan (CPT® 78306) (for skeletal symptoms)
Inconclusive conventional imaging	• PET/CT (CPT® 78815)

Evidence Discussion

Initial imaging of hepatocellular carcinoma seeks to establish the tumor burden in the liver. CT or MRI imaging is preferred over the use of ultrasound. Additionally, common sites of metastases in individuals with hepatocellular carcinoma include the lungs, adrenal glands, peritoneum, and bone. Thus, initial work-up for all newly diagnosed individuals requires chest imaging. Bone scan completes this initial work-up by allowing dedicated imaging to identify potential bone metastases if suspected. PET/CT is a useful tool for evaluating inconclusive findings on the initial imaging studies due to its limited specificity but high sensitivity.[2,8]

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Hepatocellular Carcinoma (HCC) – Restaging/Recurrence (ONC-14.4)

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Indication	Medically Necessary Imaging Study
ONE of the following: • After initial therapy • For suspected recurrence or new liver lesions • Individuals receiving systemic therapy (every 2 cycles)	• CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) And ONE of the following: • CT Abdomen with contrast (CPT® 74160) • CT Abdomen without and with contrast (CPT® 74170) • CT Abdomen and Pelvis with contrast (CPT® 74177) or CT Abdomen and Pelvis without and with contrast (CPT® 74178) • MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast
Inconclusive conventional imaging	• PET/CT (CPT® 78815)
Hepatocellular Carcinoma treated with local therapy (ablation, embolization)	See: **Liver Metastases (ONC-31.2)** for imaging studies prior to and post-procedure
Hepatocellular Carcinoma awaiting liver transplant	See: **Liver Transplant, Pre-Transplant (AB-42.1)** in the Abdomen Imaging Guidelines

Evidence Discussion

To assess response after treatment, dedicated imaging of the chest, abdomen, and pelvis are indicated. NCCN stated, "CT of the chest and CT or MRI of the abdomen and pelvis are the preferred modalities as they reliably assess intranodular arterial vascularity, a key feature of residual or recurrent tumor".[2] Thus, these studies are also recommended for suspected recurrence or new liver lesions. PET/CT remains a useful tool for evaluation of inconclusive conventional studies due to its limited sensitivity but high specificity.[2] For individuals undergoing liver embolization, CTA Abdomen can be obtained immediately prior to this procedure. In addition, either MRI or CT of the

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Abdomen with and without contrast can be obtained immediately prior and 1 month post-ablation.[2,8] ONC-31.2 provides a broader description of additional appropriate studies prior to and after embolization for liver metastases.

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Hepatocellular Carcinoma (HCC) – Surveillance/Follow-up (ONC-14.5)

ON.GI.0014.5.A
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Indication	Medically Necessary Imaging Study
Hepatocellular Carcinoma: • Treated with surgical resection • Treated with embolization • Being monitored off therapy	Every 3 months for 2 years, then every 6 months until year 5: • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) And ONE of the following: • CT Abdomen with contrast (CPT® 74160) • CT Abdomen without and with contrast (CPT® 74170) • CT Abdomen and Pelvis with contrast (CPT® 74177) or without and with contrast (CPT® 74178) • MRI Abdomen (CPT® 74183) and Pelvis (CPT® 72197) without and with contrast
Hepatocellular Carcinoma treated with liver transplant	• See: **Liver Transplant, Post-transplant Imaging (AB-42.3)** in the Abdomen Imaging Guidelines

Evidence Discussion

Individuals treated with surgical resection, embolization or being monitored off therapy, recommendation is to obtain CT Chest with or without contrast every 3 months for 2 years then every 6 months until year 5 as well as one of the following: CT Abdomen with or with/without contrast, CT Abdomen/Pelvis with or with/without contrast or MRI Abdomen/Pelvis with and without contrast. Multiphasic cross-sectional imaging with CT or MRI is preferred due to its reliability in assessing arterial vascularity, which is associated with increased risk of recurrence following treatment.[2,9,10] HCC treated with transplant is addressed in AB-42.3, Liver Transplant and Post-Transplant Imaging.

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Gallbladder and Biliary Tumors – Initial Work-up/Staging (ONC-14.6)

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Indication	Medically Necessary Imaging Study
All individuals	• CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) And ONE of the following: • CT Abdomen with contrast (CPT® 74160) • CT Abdomen without and with contrast (CPT® 74170) • CT Abdomen and Pelvis with contrast (CPT® 74177) • MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast • MRCP with 3D rendering (CPT® 74183 and CPT® 76376 or CPT® 76377)
Inconclusive liver findings on CT (if MRI not already performed)	MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast
Inconclusive findings on MRI Abdomen	• PET/CT (CPT® 78815)

Evidence Discussion

High-quality contrast-enhanced cross-sectional imaging (CT and/or MRI) of the chest, abdomen, and pelvis is recommended to evaluate tumor penetration through the wall of the gallbladder and the presence of nodal and distant metastases, and to detect the extent of direct tumor invasion of other organs/biliary system or major vascular invasion. PET/CT is a useful tool for inconclusive findings on CT/MRI, with downsides including false-positives related to inflammation of the gallbladder.[3,11,12]

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Gallbladder and Biliary Tumors – Restaging/Recurrence (ONC-14.7)

ON.GI.0014.7.A
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Indication	Medically Necessary Imaging Study
ANY of the following: • After initial therapy • For suspected recurrence or new liver lesions • Individuals receiving systemic chemotherapy (every 2 cycles)	• CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) And ONE of the following: • CT Abdomen with contrast (CPT® 74160) • CT Abdomen and Pelvis with contrast (CPT® 74177) • MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast
Inconclusive liver findings on CT (if MRI not already performed for restaging)	• MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast
Inconclusive findings on MRI Abdomen	• PET/CT (CPT® 78815)

Evidence Discussion

CT Chest with or without contrast plus one of the following: CT Abdomen with or with/without contrast, CT Abdomen/Pelvis with contrast and MRI Abdomen/Pelvis with and without contrast. High-quality contrast-enhanced cross-sectional imaging (CT and/or MRI) of the chest, abdomen, and pelvis is recommended to evaluate tumor penetration through the wall of the gallbladder and the presence of nodal and distant metastases, and to detect the extent of direct tumor invasion of other organs/biliary system or major vascular invasion. PET/CT for inconclusive findings on CT/MRI keeping in mind false positives related to an inflamed gallbladder are problematic.[3,11,12]

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Gallbladder and Biliary Tumors – Surveillance/Follow-up (ONC-14.8)

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Indication	Medically Necessary Imaging Study
All individuals	Every 3 months for 2 years, and then every 6 months up to year 5: • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) And ONE of the following: • CT Abdomen with contrast (CPT® 74160) • CT Abdomen without and with contrast (CPT® 74170) • CT Abdomen and Pelvis with contrast (CPT® 74177) • MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast
Biliary carcinoma treated with liver transplant	See: **Liver Transplant, Post-transplant Imaging (AB-42.3)** in the Abdomen Imaging Guidelines

Evidence Discussion

NCCN stated "there are no data to support a specific surveillance schedule following resection of gallbladder cancer".[3] However, NCCN did suggest consideration of imaging studies every three to six months for two years, and then every six to twelve months for up to five years. Recurrence typically occurs within two years.[3] Thus, this guideline allows for all individuals to receive imaging based upon that schedule. Biliary cancer treated with liver transplant would follow AB-42.3, Liver Transplant, Post-transplant Imaging.

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Gastric Cancer – Initial Work-up/Staging (ONC-14.9)

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Indication	Medically Necessary Imaging Study
All individuals	• CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177)
Gastric cancer ≥T2 or higher with no metastatic disease by conventional imaging	• PET/CT (CPT® 78815)

Evidence Discussion

All individuals should get CT Chest/Abdomen/Pelvis with contrast. For T2 or higher stage disease with no metastatic disease by CT, PET/CT recommended to complete staging. FDG-PET alone is not an adequate diagnostic procedure in the detection and preoperative staging of gastric cancer, but can be helpful when used in conjunction with CT.[1,13,14]

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Gastric Cancer – Restaging/Recurrence (ONC-14.10)

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Indication	Medically Necessary Imaging Study
• After initial therapy for presumed surgically resectable disease • Post curative chemoradiation being treated without surgery • For suspected recurrence	• CT Chest with contrast (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177)
Monitoring response to chemotherapy (every 2 cycles, ~every 6-8 weeks) for: • Unresected primary disease • Metastatic disease	• CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Chest with contrast (CPT® 71260)
New liver lesion(s) and primary site controlled	• CT Abdomen without and with contrast (CPT® 74170) or MRI Abdomen without and with contrast (CPT® 74183)
EITHER of the following: • Inconclusive findings on conventional imaging • Restaging of individuals with unresectable disease who cannot undergo CT with contrast due to renal insufficiency or contrast allergy	• PET/CT (CPT® 78815)

Evidence Discussion

CT Chest/Abdomen/Pelvis should be obtained after initial therapy for presumed resectable disease, post curative chemoradiation (no surgery) and for suspected recurrence. Monitoring chemotherapy response should include CT Abdomen/Pelvis and include CT Chest for known disease, new/worsening pulmonary symptoms or abnormal chest x-ray. PET/CT can be considered with inconclusive findings on conventional imaging. PET/CT is also the preferred option for imaging individuals who cannot undergo CT evaluations due to contrast allergies or renal insufficiency.[1]

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Gastric Cancer – Surveillance/Follow-up (ONC-14.11)

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Indication	Medically Necessary Imaging Study
Stage I (treated with resection alone)	• No routine imaging unless clinical signs/ symptoms of recurrence
ANY of the following: • Stage I treated with systemic therapy • Stages II-III • Stage IV - Metastatic disease with no measurable disease post definitive treatment	Every 6 months for 2 years, and then annually for 3 more years: • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) and CT Abdomen and Pelvis with contrast (CPT® 74177) ◦ In individuals who cannot undergo CT with contrast due to renal insufficiency or contrast allergy, MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197) are the medically necessary substitute.
Measurable metastatic disease on maintenance therapy or being monitored off therapy	Every 3 months for up to 5 years after completion of active treatment: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177)

Evidence Discussion

Stage I treated with resection alone does not require routine imaging in the absence of signs/symptoms of recurrence. Stage I treated with systemic therapy, Stages II-III and Stage IV s/p definitive treatment of all measurable disease or being observed off therapy should undergo CT Chest/Abdomen/Pelvis every 6 months for 2 years then annually up to 5 years. Measurable metastatic disease on maintenance therapy or being monitored off therapy should undergo CT Chest/Abdomen/Pelvis every 3 months for up to 5 years after completion of active treatment.[1]

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Neuroendocrine Cancers and Adrenal Tumors (ONC-15)

Guideline

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Gastrointestinal/Pancreatic Neuroendocrine Cancers – Suspected/Diagnosis (ONC-15.2)
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General Considerations (ONC-15.1)

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This guideline includes low-grade or well-differentiated carcinoid and endocrine tumors of the lung, thymus, pancreas, gastrointestinal tract or unknown primary site; including insulinoma, glucagonoma, VIPoma, gastrinoma, somatostatinoma and others as well as catecholamine-secreting tumors of the adrenal gland such as pheochromocytoma, paraganglioma, adrenocortical carcinoma, and others.

- For poorly-differentiated or high-grade small cell or large cell neuroendocrine tumors arising outside the lung or from an unknown primary site, see: **Extrathoracic Small Cell and Large Cell Neuroendocrine Tumors (ONC-31.8)**.
- For poorly-differentiated or high-grade neuroendocrine tumors of the lung, see: **Small Cell Lung Cancer (ONC-7)**.
- Neuroblastoma, ganglioneuroblastoma, and ganglioneuroma occurring in adults should be imaged according to **Neuroblastoma (PEDONC-6)** in the Pediatric and Special Populations Oncology Imaging Guidelines.
- Many are associated with Multiple Endocrine Neoplasia (MEN) familial syndromes.
  – See: **Multiple Endocrine Neoplasias (MEN) (PEDONC-2.8)** in the Pediatric and Special Populations Oncology Imaging Guidelines for screening recommendations.
- Somatostatin receptor (SSR) based imaging is more sensitive and specific for evaluation of well-differentiated neuroendocrine tumors and may be performed using ^{111}In DTPA Octreotide scintigraphy or PET/CT scan with SSR radiotracers (such as ^{68}Ga–DOTATATE, ^{68}Ga-DOTATOC, or ^{64}Cu-DOTATATE). This study is not part of evaluation of poorly-differentiated or high-grade neuroendocrine tumors, which are imaged according to: **Extrathoracic Small Cell and Large Cell Neuroendocrine Tumors (ONC-31.8)**.

Evidence Discussion

This guideline includes low-grade or well-differentiated (Grade 1, 2, or 3; Ki-67 >20% and <55%) carcinoid and endocrine tumors of the lung, thymus, pancreas, gastrointestinal tract or unknown primary site; including insulinoma, glucagonoma, VIPoma, gastrinoma, somatostatinoma and others as well as catecholamine-secreting tumors of the adrenal gland such as pheochromocytoma, paraganglioma, adrenocortical carcinoma, and others. These tumors are particularly sensitive and specific to somatostatin receptor (SSR) based imaging (nearly 80% express SSR on the cell surface) while poorly differentiated or high-grade tumors typically are not with imaging recommendations being addressed in separate guidelines.[1,9]

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Gastrointestinal/Pancreatic Neuroendocrine Cancers – Suspected/ Diagnosis (ONC-15.2)

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Indication	Medically Necessary Imaging Study
• Systemic symptoms strongly suggestive of functioning neuroendocrine tumor • Suspicious findings on other imaging studies • Unexplained elevation in ANY of the following: ◦ Chromogranin A ◦ 5HIAA ◦ Insulin ◦ VIP ◦ Glucagon ◦ Gastrin ◦ Substance P ◦ Serotonin ◦ Somatostatin	ANY of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) or without and with contrast (CPT® 74178) **OR** MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) • CT with contrast or MRI without and with contrast of any other symptomatic body areas

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Indication	Medically Necessary Imaging Study
• Continued suspicion with negative/ inconclusive CT or MRI	ONE of the following: • PET/CT (CPT® 78815) or PET/MRI (CPT® 78813 and CPT® 76498) with any ONE of the following SSR radiotracers: ◦ ^{68}Ga-DOTATATE ◦ ^{68}Ga-DOTATOC ◦ ^{64}Cu-DOTATATE • If PET/CT is not available, octreotide scan ◦ Any one of the following planar imaging codes - CPT® 78801, 78802, or 78804 **AND** ◦ Any one of the follow SPECT/SPECT-CT codes - CPT® 78803, 78830, 78831, 78832

Evidence Discussion

Neuroendocrine tumors (NETs) arise from cells of the endocrine system that can be found throughout the body. They can occur sporadically or arise in the context of an inherited genetic syndrome. Presentation is usually attributable to hormonal hypersecretion (functional tumors) that can include flushing/diarrhea/wheezing (Carcinoid syndrome), hypertension and hypoglycemia versus being found incidentally on various imaging studies. If these symptoms/signs are suspicious for a NET, appropriate serologic/urinary workup may include chromogranin A, 5HIAA, insulin, VIP, glucagon, gastrin, substance P, serotonin and somatostatin. If these markers are elevated, CT chest with or without contrast as well as CT or MRI of abdomen/pelvis/ any other symptomatic body area is indicated. CT is best for detection of primary small bowel lesions and lymphadenopathy while MRI is preferred for pancreatic NETs and detecting hepatic metastases. If these imaging studies are negative/inconclusive, SSR based imaging with either Octreotide scan or Dotatate/Dotatoc (Gallium-68, Copper-64) may be indicated (SSR PET/CT). All three of these functional imaging modalities are FDA approved and can be performed in individuals on somatostatin analog therapy and are considered to be superior to Octreotide scan. FDG-based PET/CT has limited use as the majority of NETs are metabolically inactive and fail to take up the tracer well.[1,9,10,11]

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Gastrointestinal/Pancreatic Neuroendocrine Cancers – Initial Work-up/Staging (ONC-15.3)

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- For undifferentiated neuroendocrine tumors, see: **Extrathoracic Small Cell and Large Cell Neuroendocrine Tumors ONC-31.8**

Indication	Medically Necessary Imaging Study
ANY of the following: • Jejunal • Ileal • Colon • Gastric type 3 • Neuroendocrine tumors of unknown primary • Grade 3 well-differentiated tumors	If not already done, ANY or ALL of the following: • PET/CT (CPT® 78815) or PET/MRI (CPT® 78813 and CPT® 76498) with any ONE of the following SSR radiotracers: ◦ 68Ga-DOTATATE ◦ 68Ga-DOTATOC ◦ 64Cu-DOTATATE • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) • And ONE of the following: ◦ CT Abdomen and Pelvis with contrast (CPT® 74177) ◦ CT Abdomen and Pelvis without and with contrast (CPT® 74178) ◦ MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast

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Indication	Medically Necessary Imaging Study
All other GI or pancreatic neuroendocrine (carcinoid) tumors	If not already done: • CT Abdomen and Pelvis with contrast (CPT® 74177) or without and with contrast (CPT® 74178) OR MRI Abdomen (CPT® 74183) and Pelvis (CPT® 72197) without and with contrast • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250)
Inconclusive CT or MRI scans	ONE of the following: • PET/CT (CPT® 78815) or PET/MRI (CPT® 78813 and CPT® 76498) with any ONE of the following SSR radiotracers: ◦ ^{68}Ga-DOTATATE ◦ ^{68}Ga-DOTATOC ◦ ^{64}Cu-DOTATATE • If PET is not available, octreotide scan (ANY one of the following): ◦ Any one of the following planar imaging codes - CPT® 78801, 78802, or 78804 AND ◦ Any one of the following SPECT/SPECT-CT codes - CPT® 78803, 78830, 78831, 78832
ANY of the following: • Markers fail to normalize after complete resection AND CT/MRI and somatostatin-receptor based study are negative • Biopsy-proven neuroendocrine tumor of unknown primary site AND CT/MRI and somatostatin-receptor based study are negative	• FDG-PET/CT (CPT® 78815)

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Evidence Discussion

For initial evaluation of all neuroendocrine tumors, the National Comprehensive Cancer Network (NCCN) recommended that cross-sectional imaging be performed of the primary site of disease utilizing either CT or MRI. Imaging with chest CT is also an NCCN recommended consideration. For certain disease types including neuroendocrine tumors of the jejunum, ileum, and colon, as well as gastric type 3, neuroendocrine tumors of unknown primary, and grade 3 well-differentiated tumors, the NCCN recommends that a PET/CT or PET/MRI utilizing SSR radiotracers be performed in addition to diagnostic CT or MRI imaging. Brain imaging is not generally recommended for well-differentiated NET without signs and symptoms of neurologic involvement. The NCCN states octreotide scans are "much less sensitive for defining SSTR-positive disease than PET". Thus, these guidelines reserve octreotide scans as a problem-solving tool if PET is inconclusive or not available.[1,10,11]

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Gastrointestinal/Pancreatic Neuroendocrine Cancers – Restaging/ Recurrence (ONC-15.4)

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Indication	Medically Necessary Imaging Study
All after surgical resection	• See: **Gastrointestinal/Pancreatic Neuroendocrine Cancers – Surveillance (ONC-15.5)**
Unresectable/metastatic disease on treatment with somatostatin analogues	• CT or MRI of involved body area no more frequently than every 3 months
Unresectable/metastatic disease on treatment with chemotherapy	• CT or MRI of involved body area every 2 cycles (6 to 8 weeks)
Suspected recurrence	• PET/CT (CPT® 78815) or PET/MRI (CPT® 78813 and CPT® 76498) with any ONE of the following SSR radiotracers: ◦ ^{68}Ga-DOTATATE ◦ ^{68}Ga-DOTATOC ◦ ^{64}Cu-DOTATATE AND • CT Chest without contrast (CPT® 71250) or CT Chest with contrast (CPT® 71260) And ONE of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen and Pelvis without and with contrast (CPT® 74178) • MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast

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Indication	Medically Necessary Imaging Study
Continued suspicion for recurrence with negative or inconclusive CT or MRI, and PET not available	• Octreotide scan: ◦ Any one of the following planar imaging codes - CPT® 78801, 78802, or 78804 **AND** ◦ Any one of the following SPECT/SPECT-CT codes - CPT® 78803, 78830, 78831, 78832
To assess candidacy for peptide receptor radionuclide therapy (PRRT) with Lutetium ^{177}Lu-dotatate	• PET/CT (CPT® 78815) or PET/MRI (CPT® 78813 and CPT® 76498) with any ONE of the following SSR radiotracers: ◦ ^{68}Ga-DOTATATE ◦ ^{68}Ga-DOTATOC ◦ ^{64}Cu-DOTATATE

Evidence Discussion

NCCN recommended that for any suspected recurrence of disease, PET/CT or PET/MRI be performed in addition to systemic diagnostic imaging. For individuals with unresectable/metastatic disease, NCCN stated that "anatomic imaging should generally be performed every 12 weeks-12 months based on clinical or pathologic signs of aggressiveness". Thus, CT imaging of involved body area is recommended every 3 months if on somatostatin therapy versus every 2 cycles (6-8 weeks) if on chemotherapy. To assess for candidacy for peptide receptor radionuclide therapy (PRRT) with Lutetium Lu-177 dotatate (Lutathera), any of the 3 SSR PET/CT or PET/MRI options are supported. The NCCN stated octreotide scans are "much less sensitive for defining SSTR-positive disease than PET". Thus, these guidelines reserve octreotide scans as a problem-solving tool if PET is inconclusive or not available.[1]

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Gastrointestinal/Pancreatic Neuroendocrine Cancers – Surveillance (ONC-15.5)

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Indication	Medically Necessary Imaging Study
ANY of the following: • Appendix carcinoid <1 cm, completely resected • Rectal carcinoid <1 cm, completely resected • Gastric carcinoid treated with complete endoscopic resection	• Advanced imaging is not medically necessary for surveillance
Rectal carcinoid 1-2 cm, completely resected	• MRI Pelvis without and with contrast (CPT® 72197) at 6 and 12 months post resection. No further routine surveillance.
All other GI neuroendocrine tumors (stomach, large and small intestine)	• CT Abdomen and Pelvis with contrast (CPT® 74177) or MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast once at 3 to 12 months post-operatively and every 12-24 months up to year 10 ◦
Unresected GI neuroendocrine tumors being monitored with observation alone	• CT Abdomen with contrast (CPT® 74160) once at 3 to 12 months from initial diagnosis, then every 3 months for 1 year, then every 6 months in year 2, and then annually up to year 10
Pancreatic neuroendocrine tumors	• CT Abdomen with contrast (CPT® 74160) once at 3 to 12 months post-operatively then annually up to year 10

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Indication	Medically Necessary Imaging Study
Unresected pancreatic neuroendocrine tumors being monitored with observation alone	• CT Abdomen with contrast (CPT® 74160) once at 3 to 12 months from initial diagnosis then annually up to year 10
Measurable metastatic disease on maintenance treatment or off therapy	• CT of involved body area no more frequently than every 3 months

Evidence Discussion

In the absence of signs/symptoms of recurrence, advanced imaging is not routinely indicated for completely resected appendiceal carcinoid <1 cm, completely resected rectal carcinoid <1 cm, and gastric carcinoid treated with complete endoscopic resection due to their excellent prognosis and low risk of recurrence.[6,13] For completely resected rectal carcinoid 1-2 cm, MRI pelvis with and without contrast at 6 and 12 months post-resection and if clear, no further imaging. Due to the indolent nature of NETs, long term follow-up is recommended. For all other GI NETs, CT or MRI abdomen/pelvis once 3-12 months post-operatively and then every 12-24 months for 10 years is supported by NCCN. Unresected GI NETs on observation should undergo CT abdomen with contrast once at 3-12 months from initial diagnosis then annually up to year 10. Resected pancreatic NETs should undergo CT abdomen with contrast once at 3-12 months post-operatively then annually up to year 10. Unresected pancreatic NETs should undergo CT Abdomen with contrast once at 3-12 months from initial diagnosis then annually up to year 10. For individuals with measurable metastatic disease on maintenance or off therapy, CT of involved body area no more frequently than every 3 months. After 10 years, surveillance should be as clinically indicated.[1]

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Bronchopulmonary or Thymic Carcinoid – Initial Staging (ONC-15.6)

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Indication	Medically Necessary Imaging Study
Initial diagnosis	If not already done: • CT Chest with contrast (CPT® 71260) • CT Abdomen with contrast (CPT® 74160) or without and with contrast (CPT® 74170) or MRI Abdomen (CPT® 74183) without and with contrast
Inconclusive CT or MRI scans	ONE of the following: • Octreotide scan (ANY ONE of the following): ◦ Any one of the following planar imaging codes - CPT® 78801, 78802, or 78804 **AND** ◦ Any one of the following SPECT/SPECT-CT codes - CPT® 78803, 78830, 78831, 78832 • PET/CT (CPT® 78815) or PET/MRI (CPT® 78813 and CPT® 76498) with any ONE of the following SSR radiotracers: ◦ ^{68}Ga-DOTATATE ◦ ^{68}Ga-DOTATOC ◦ ^{64}Cu-DOTATATE

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Indication	Medically Necessary Imaging Study
ANY of the following: • Markers fail to normalize after complete resection AND CT/MRI and somatostatin-receptor based study are negative • Biopsy-proven neuroendocrine tumor of unknown primary site AND CT/MRI and somatostatin-receptor based study are negative	• FDG-PET/CT (CPT® 78815) OR PET/MRI (CPT® 78813 and CPT® 76498)

Evidence Discussion

More than 80% of lung carcinoids are diagnosed at Stage I or II with the most common sites of metastases being liver, bone, and lung.[14] Most thymic carcinoids are diagnosed at Stage III or IV with the most common sites of metastases being pleura, pericardium, bone, lung, and liver. Recommended initial imaging includes CT Chest with contrast and CT or MRI of the abdomen. Imaging of the brain, pelvis or osseous structures is based on signs/symptoms of disease. If the CT/MRI is inconclusive, Octreotide scan or SSR-based PET can be completed. In the setting where markers fail to normalize after surgery AND CT/MRI and SSR based study are negative OR there is biopsy proven NET of unknown origin AND CT/MRI and SSR based study are negative, FDG-based PET is indicated for the concern of a higher-grade NET being present.[10,11]

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Bronchopulmonary or Thymic Carcinoid – Restaging/Recurrence (ONC-15.7)

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Indication	Medically Necessary Imaging Study
All after surgical resection	• See: **Bronchopulmonary or Thymic Carcinoid - Surveillance (ONC-15.8)**
Unresectable/metastatic disease on treatment with somatostatin analogues	• CT or MRI of involved body area no more frequently than every 3 months
Unresectable/metastatic disease on treatment with chemotherapy	• CT or MRI of involved body area every 2 cycles (6 to 8 weeks)
Progression of symptoms or elevation of tumor markers	• CT Chest without (CPT® 71250) or CT Chest with contrast (CPT® 71260) And ONE of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen and Pelvis without and with contrast (CPT® 74178) • MRI Abdomen (CPT® 74183) and Pelvis (CPT® 72197) without and with contrast

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Indication	Medically Necessary Imaging Study
Continued suspicion for recurrence with negative or inconclusive CT or MRI	ONE of the following: • Octreotide scan ◦ Any one of the following planar imaging codes - CPT® 78801, 78802, or 78804 **AND** ◦ Any one of the following SPECT/SPECT-CT codes - CPT® 78803, 78830, 78831, 78832 • PET/CT (CPT® 78815) or PET/MRI (CPT® 78813 and CPT® 76498)with any ONE of the following SSR radiotracers: ◦ ^{68}Ga-DOTATATE ◦ ^{68}Ga-DOTATOC ◦ ^{64}Cu-DOTATATE

Evidence Discussion

For individuals with unresectable/metastatic disease, CT imaging of involved body area is recommended every 3 months if on somatostatin therapy versus every 2 cycles (6-8 weeks) if on chemotherapy. CT Chest and CT/MRI Abdomen/Pelvis is indicated for progression of symptoms or elevation of tumor markers while Octreotide scan or SSR PET if conventional imaging is negative/inconclusive.[10,11]

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Bronchopulmonary or Thymic Carcinoid – Surveillance (ONC-15.8)

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Indication	Medically Necessary Imaging Study
Carcinoid tumors of lung or thymus	• CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) and CT Abdomen with contrast (CPT® 74160) once at 3 to 12 months post-resection and then annually up to year 10
Unresected primary tumors being monitored with observation alone	• CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) and CT Abdomen with contrast (CPT® 74160) once at 3 to 12 months from initial diagnosis then annually up to year 10
Asymptomatic lung or thymus distant metastasis on observation alone	Every 3 months for 1 year, and then every 6 months: • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) • CT Abdomen and Pelvis with contrast (CPT® 74177) or MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast
Measurable metastatic disease on maintenance treatment or off therapy	• CT Chest with contrast (CPT® 71260) • CT of involved body area no more frequently than every 3 months

Evidence Discussion

For carcinoid tumors of the lung or thymus, prognosis varies. In typical lung carcinoid, 5-year and 10-year overall survival (OS) is approximately 81% to 96% and 74% to 91% respectively for both node negative and node positive disease. With atypical histology, 5-year OS is 82% to 90% in node negative disease and 58-71% in node positive disease. Thymic carcinoid 5-year OS is <50%. Due to lack of long-term follow-up imaging studies, it is recommended to minimize risk of radiation exposure using CT or MRI.[14] In individuals with resected disease, CT Chest 3-12 months post resection and then annually for up to 3 years then every 2 years up to year 10. Unresected primary tumors on observation follow a similar schedule with CT Chest 3-12 months from initial diagnosis and then annually for up to 3 years then every 2 years up to year 10. Measurable metastatic disease on maintenance therapy or observation undergoes CT of

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involved body area no more frequently than every 3 months. After 10 years, surveillance should be as clinically indicated.[1]

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Adrenal Tumors – Suspected/Diagnosis (ONC-15.9)

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- See: **Adrenal Cortical Lesions (AB-16.1)** in the Abdomen Imaging Guidelines for evaluation of indeterminate adrenal masses.
- Adrenal tumors that involve the adrenal medulla or neural crest tissue outside the adrenal gland include pheochromocytoma, paraganglioma, and paraganglioneuroma.
  - These tumors are imaged according to sections **ONC-15.10 through ONC-15.12**.
  - Malignant adrenal tumors that involve the adrenal cortex are addressed in **Adrenocortical Carcinoma (ONC-15.13).**
- Adrenocortical carcinoma is imaged according to **Adrenocortical Carcinoma (ONC-15.13)**.
- If concern for genetic predisposition syndrome such as MEN, neurofibromatosis, or Von Hippel-Lindau disease, see screening recommendations in **Screening Imaging and Cancer Predisposition Syndromes (PEDONC-2)** in the Pediatric and Special Populations Oncology Imaging Guidelines.

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Adrenal Tumors – Initial Work-up/Staging (ONC-15.10)

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- This guideline can be applied to **any primary site** (including beyond adrenal gland) for pheochromocytoma, paraganglioma, or paraganglioneuroma.

Indication	Medically Necessary Imaging Study
For ANY of the following: • Pheochromocytoma • Paraganglioma • Paraganglioneuroma	If not already done: • CT Chest without (CPT® 71250) or CT Chest with contrast (CPT® 71260) And ONE of the following (if not already done): • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen and Pelvis without and with contrast (CPT® 74178) • MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast • CT with contrast or MRI without and with contrast of primary site (i.e., neck) and any other symptomatic body areas
Hypercortisolemia with ANY of the following: • Tumor greater than 4 cm • Inhomogeneous • Irregular margins • Local invasion • Other malignant imaging characteristics	ANY or ALL of the following: • FDG PET/CT (CPT® 78815) • CT Abdomen with contrast (CPT® 74160) or CT Abdomen without and with contrast (CPT® 74170) or MRI Abdomen without and with contrast (CPT® 74183)

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Indication	Medically Necessary Imaging Study
Continued suspicion with negative/ inconclusive CT or MRI	ONE of the following: • Octreotide or MIBG scan: ◦ Any one of the following planar imaging codes - CPT® 78801, 78802, 78804 **AND** ◦ Any one of the following SPECT/SPECT-CT codes - CPT® 78803, 78830, 78831, 78832 • PET/CT (CPT® 78815) or PET/MRI (CPT® 78813 and CPT® 76498) with any ONE of the following SSR radiotracers: ◦ ^{68}Ga-DOTATATE ◦ ^{68}Ga-DOTATOC ◦ ^{64}Cu-DOTATATE
All above studies done and negative/ inconclusive	• FDG PET/CT scan (CPT® 78815)

Evidence Discussion

Radiologic evaluation of adrenal tumors should follow biochemical conformation of the diagnosis of pheochromocytoma and paraganglioglioma. Ninety-five percent of this group of tumors occur in the abdomen and pelvis. Paragangliomas account for 15% of this group of tumors. The initial work-up/staging of this group of tumors includes CT Chest (with contrast or without contrast) as approximately 10% of paragangliomas are found in the chest and pheochromocytoma has a potential to metastasize to chest. CT imaging with or without and with contrast or MRI imaging without and with contrast of the abdomen, pelvis and any other symptomatic body areas are indicated for initial staging. Hypercortisolemia can be caused by benign and malignant tumors. NCCN stated, "Malignancy should be suspected if the tumor is larger than 4 centimeters or is inhomogeneous with irregular margins and/or has local invasion and other malignant imaging characteristics" and went on to recommend imaging with PET/CT, CT Chest, and CT or MRI abdominal imaging.[1]

Functional imaging is a valuable problem-solving tool when there is continued suspicion for this group of tumors with inconclusive or negative findings on CT/MRI. ^{123}I/ ^{131}I-MIBG sensitivity is higher for detecting pheochromocytoma than for detecting paraganglioma, at 88% and 67%, respectively. Another approach to functional imaging utilizes ^{68}Ga-DOTA-somatostatin analogs including DOTATOC, DOTANOC, and DOTATATE (SSR-PET/CT. In meta-analyses, the sensitivity of 68Ga-DOTA-somatostatin

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analogs (93%) is superior to ^{18}F-FDG (74%), and ^{123}I/ ^{131}I-MIBG (38%). Imaging with ^{111}In-pentetreotide (octreotide) (24%) is less sensitive that imaging with ^{68}Ga-DOTA-somatostatin analogs. Of note, functional imaging using ^{18}F-FDG PET/CT can be useful for evaluation in the scenario that CT/MRI and other functional imaging studies are negative/inconclusive.[1,15-18]

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Adrenal Tumors – Restaging/Recurrence (ONC-15.11)

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- This guideline can be applied to **any primary site** (including beyond adrenal gland) for pheochromocytoma, paraganglioma, or paraganglioneuroma.

Indication	Medically Necessary Imaging Study
If surgery is primary therapy	See: **ONC-15.12** for surveillance recommendations
Recurrence, progression of symptoms, or elevation of tumor markers	• CT Chest without contrast (CPT® 71250) or CT Chest with contrast (CPT® 71260) • CT with contrast of primary site (i.e., neck) and involved areas And ONE of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen and Pelvis without and with contrast (CPT® 74178) • MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast
Continued suspicion for recurrence with negative or inconclusive CT or MRI	ONE of the following: • Octreotide or MIBG scan (ANY ONE of the following): ◦ Any one of the following planar imaging codes - CPT® 78801, 78802, or 78804 **AND** ◦ Any one of the following SPECT/SPECT-CT codes - CPT® 78803, 78830, 78831, 78832 • PET/CT (CPT® 78815) or PET/MRI (CPT® 78813 and CPT® 76498) with any ONE of the following SSR radiotracers: ◦ ^{68}Ga-DOTATATE ◦ ^{68}Ga-DOTATOC ◦ ^{64}Cu-DOTATATE

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Indication	Medically Necessary Imaging Study
To assess candidacy for peptide receptor radionuclide therapy (PRRT) with Lutetium ^{177}Lu-dotatate	• PET/CT (CPT® 78815) or PET/MRI (CPT® 78813 and CPT® 76498) with any ONE of the following SSR radiotracers: ◦ ^{68}Ga-DOTATATE ◦ ^{68}Ga-DOTATOC ◦ ^{64}CU-DOTATATE
For ANY of the following: • All above studies done and negative/ inconclusive • Hypercortisolemia with inconclusive findings on CT • Pheochromocytoma bone-dominant disease • Paraganglioma bone-dominant disease	• FDG-PET/CT scan (CPT® 78815)

Evidence Discussion

In individuals who underwent surgery for resection of localized disease, CT Abdomen with contrast is supported within the first year post resection. Follow-up imaging is based on surveillance recommendations noted in Adrenal Tumors – Surveillance (ONC 15.12). In individuals who develop recurrence, progression of symptoms or elevation of tumor markers, the extent of disease must be determined with CT/MRI imaging. CT chest (with contrast or without contrast), CT imaging with or without and with contrast or MRI imaging without and with contrast of the abdomen, pelvis and any any other symptomatic body areas are indicated. Functional imaging with ^{111}In-pentetreotide (octreotide scan) or ^{68}Ga-DOTA-somatostatin analog PET is a valuable problem solving tool when there is continued suspicion of recurrence with inconclusive or negative findings on CT/MRI. Further evaluation using ^{18}F-FDG PET/CT can be useful for evaluation in the scenario that CT/MRI and other functional imaging studies are negative/inconclusive. ^{18}F-FDG PET/CT is also supported by NCCN for the evaluation of hypercortisolemia with inconclusive findings on CT, pheochromocytoma bone-dominant disease, and paraganglioma bone-dominant disease.[1,15-18]

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Adrenal Tumors – Surveillance (ONC-15.12)

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- This guideline can be applied to **any primary site** (including beyond adrenal gland) for pheochromocytoma, paraganglioma, paraganglioneuroma, or hypercortisolemia.

Indication	Medically Necessary Imaging Study
All individuals	Once within 3-12 months post resection and then annually for 10 years: • CT Chest with contrast (CPT® 71260) or without contrast (CPT® 71250) • CT Abdomen and Pelvis with contrast (CPT® 74177) or MRI Abdomen and Pelvis without and with contrast (CPT® 74183 and 72197) • CT with contrast of primary site (i.e., neck) and other involved body areas
Measurable metastatic disease being observed off therapy or on maintenance treatment	• CT of involved body area no more frequently than every 3 months for up to 5 years after completion of definitive therapy and annually thereafter

Evidence Discussion

In individuals who had resectable disease, CT imaging of the chest and either CT or MR imaging of the abdomen, pelvis, and any other previously involved body areas are indicated once within 3-12 months post resection then annually for 10 years. In individuals with measurable metastatic disease being observed off therapy or on maintenance therapy are at greater risk for recurrence. In addition to the imaging schedule noted above, imaging of the involved body area is indicated with greater frequency (3 months) for up to 5 years followed by annual imaging.[1,15-18]

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Adrenocortical Carcinoma (ONC-15.13)

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Indication	Medically Necessary Imaging Study
Initial Staging	• FDG PET/CT (CPT® 78815) • CT Chest without (CPT® 71250) or CT Chest with contrast (CPT® 71260) And ONE of the following (if not already done): • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen and Pelvis without and with contrast (CPT® 74178) • MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast
Suspected recurrence	• CT Chest without (CPT® 71250) or CT Chest with contrast (CPT® 71260) And ONE of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen and Pelvis without and with contrast (CPT® 74178) • MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast
• Inconclusive findings on conventional imaging	• FDG PET/CT (CPT® 78815)
Surveillance after complete response to definitive treatment	Annually for 5 years: • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) • CT Abdomen with contrast (CPT® 74160) or MRI Abdomen (CPT® 74183) without and with contrast • CT of other involved body areas with contrast

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Indication	Medically Necessary Imaging Study
Measurable metastatic disease on maintenance therapy or being monitored off therapy	Every 3 months for up to 5 years after completion of definitive therapy: • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) • CT Abdomen and Pelvis with contrast (CPT® 74177) or MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast • CT with contrast of other involved body areas

Evidence Discussion

Adrenocortical carcinoma (ACC) is a rare, aggressive tumor arising from the adrenal cortex. Most cases of ACC are sporadic; however, ACC has been described as a component of hereditary cancer syndromes that include Li-Fraumeni syndrome, Beckwith-Weidemann syndrome and multiple endocrine neoplasia type 1 (MEN1). Recommended imaging guidelines for screening of individuals with these syndromes are summarized in Screening Imaging in Cancer Predisposition Syndromes (PEDONC-2). ACCs that secrete excess adrenal hormones are classified as functional tumors and occur in 15-30% of cases in adults. Those patients with functional tumors present with Cushing's syndrome and/or virilization. The majority of adults with non-functioning ACCs present symptomatically with abdominal pain or flank pain; however, these tumors may present asymptomatically as a large palpable intra-abdominal mass or incidentally as a small adrenal mass. Approximately 30% of ACCs present with metastatic disease in lymph nodes, lung, live and bone. ACCs may also present with invasion of adjacent structures and with venous extension.

CT and MRI cross-sectional imaging are the standard imaging modalities used for the evaluation of ACC. Due to the measurable risk for widely metastatic disease at initial presentation, cross-section imaging of the chest and abdomen/pelvis is indicated. CT Chest (with contrast or without contrast) is indicated to evaluate for lung metastases. Cross-sectional imaging of the abdomen/pelvis using CT Abdomen/Pelvis (with or with and without contrast) or MRI Abdomen as well as MRI Pelvis (with and without contrast) are indicated for characterization of the primary tumor and evaluation for metastatic disease. If recurrence is suspected, the same imaging studies should be completed as was done for initial staging. Additional imaging may be needed to assess other suspicious sites of disease based on clinical signs/symptoms.

NCCN endorsed the use of FDG PET/CT in addition to diagnostic CT or MRI for initial imaging of suspected adrenocortical carcinoma. FDG PET/CT scan is a valuable

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problem-solving tool; thus, FDG PET/CT is supported to characterize inconclusive findings CT/MRI.

CT imaging is the standard approach in surveillance. In individuals who had complete response to definitive therapy, the recommendation is annual imaging for 5 years after completion of treatment as the rate of recurrence is <25% and overall survival rate approaches 74% to 95% at 5 years. In individuals with metastatic disease on maintenance therapy or being monitored off treatment, the frequency of CT imaging is shortened and repeated at 3 month intervals for up to 5 years.[1,19-22]

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Colorectal and Small Bowel Cancer (ONC-16)

Guideline

Colorectal Cancer – General Considerations (ONC-16.0)
Colorectal Cancer – Suspected/Diagnosis (ONC-16.1)
Colorectal Cancer – Initial Work-up/Staging (ONC-16.2)
Colorectal Cancer – Restaging/Recurrence (ONC-16.3)
Colorectal Cancer – Surveillance/Follow-up (ONC-16.4)
Small Bowel Cancer – Initial Work-up/Staging (ONC-16.5)
Small Bowel Cancer – Restaging/Recurrence (ONC-16.6)
Small Bowel Cancer – Surveillance/Follow-up (ONC-16.7)
References (ONC-16)

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Colorectal Cancer – General Considerations (ONC-16.0)

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- Neuroendocrine tumors of the bowel are covered in: **Neuroendocrine Cancers and Adrenal Tumors (ONC-15)**.
- Appendiceal adenocarcinoma (including pseudomyxoma peritonei) follows imaging guidelines for colorectal cancer.
- For squamous cell carcinoma of the rectum, see: **Anal Carcinoma (ONC-24)**.

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Colorectal Cancer – Suspected/ Diagnosis (ONC-16.1)

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- See: **GI Bleeding (AB-22)** or **CT Colonography (CTC) (AB-25.1)** in the Abdomen Imaging Guidelines for evaluation of suspected colorectal malignancies.
- See: **Abnormal Findings on Endoscopy/Colonoscopy (AB-13.3)** in the Abdomen Imaging Guidelines for evaluation of abnormal findings on endoscopy/colonoscopy.

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Colorectal Cancer – Initial Work-up/ Staging (ONC-16.2)

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Indication	Medically Necessary Imaging Study
Carcinoma within a polyp that is completely removed	• No advanced imaging
• Biopsy-proven invasive adenocarcinoma	• CT Chest with contrast (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177)
• Further evaluation of an inconclusive liver lesion seen on CT • Potentially resectable liver metastases	• MRI Abdomen without and with contrast (CPT® 74183)
Rectal adenocarcinoma	• MRI Pelvis without and with contrast (CPT® 72197) or MRI Pelvis without contrast (CPT® 72195) (can be obtained in addition to CT scans for initial staging)
Rectal adenocarcinoma with ANY one of the following: • Rectal MRI is contraindicated • Rectal MRI is inconclusive • Superficial lesions	• Endorectal ultrasound (CPT® 76872)
ONE of the following: • Isolated metastatic lesion(s) on other imaging and individual is a candidate for aggressive surgical resection or other localized treatment to metastasis for curative intent • Inconclusive conventional imaging	• PET/CT (CPT® 78815)

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Evidence Discussion

- Carcinoma within a polyp that is completely resected does not require advanced imaging.[1]
- Invasive cancer at any stage requires advanced imaging with CT of Chest/Abdomen/Pelvis with contrast needed to adequately visualize lung, nodal, and especially liver lesions with MRI of abdomen appropriate in the event of unclear liver lesions. The chest CT can identify lung metastases, which occur in approximately 4% - 9% of individuals with colon and rectal cancer.[11]
- Rectal cancer requires additional dedicated imaging with MRI Pelvis that is superior to CT imaging to locally stage this form of colon cancer with endorectal/endoscopic ultrasound (EUS), providing additional staging information when MRI is contraindicated/inconclusive/superficial. MRI is considered superior to EUS due to the latter's limitations in regard to high/bulky tumors, tumor deposits, or vascular invasion.[12]
- PET/CT is reserved for inconclusive CT/MRI imaging and to confirm isolated metastases that are amenable to definitive localized treatment with curative intent.[1]

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Colorectal Cancer – Restaging/ Recurrence (ONC-16.3)

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Indication	Medically Necessary Imaging Study
• Complete resection • Individuals receiving post-operative adjuvant chemotherapy	• See: **Surveillance/Follow-up (ONC-16.4)**
Recurrence suspected (i.e., signs or symptoms, elevated CEA)	• CT Chest with contrast (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast
After completion of planned neoadjuvant therapy	Prior to surgical resection in individuals with non-metastatic rectal cancer: • CT Chest with contrast (CPT® 71260) and Any ONE of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen with contrast (CPT® 74160) and MRI Pelvis without and with contrast (CPT® 72197)
Unresected primary disease or metastatic disease on chemotherapy	Every 2 cycles of chemotherapy treatment and at the completion of chemoradiotherapy: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of other involved or symptomatic areas
• Further evaluation of an inconclusive liver lesion seen on CT • Potentially resectable liver metastases	• MRI Abdomen without and with contrast (CPT® 74183)

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Indication	Medically Necessary Imaging Study
ONE of the following: • Postoperative elevated or rising CEA or LFTs with negative recent conventional imaging • Isolated metastatic lesion(s) on other imaging and individual is a candidate for aggressive surgical resection or other localized treatment to metastasis for curative intent • Differentiate local tumor recurrence from postoperative and/or post-radiation scarring	• PET/CT (CPT® 78815)
New or worsening pelvic pain and recent CT imaging negative or inconclusive	• MRI Pelvis without and with contrast (CPT® 72197)

Evidence Discussion

- If recurrence is suspected, CT Chest/Abdomen/Pelvis with contrast is the first line of imaging.[1]
- NCCN stated that ctDNA is not recommended for surveillance.[1]
- Upon completion of neoadjuvant therapy, to ensure the cancer has not progressed prior to definitive surgery, repeat imaging of the chest, abdomen and pelvis is medically necessary.[1]
- With measurable disease or unresected primary disease on chemotherapy, CT imaging is medically necessary every 2 cycles of treatment to assess response and appropriateness to continue the same treatment or change to new therapy.[1]
- MRI Abdomen is medically necessary for inconclusive liver lesion or to better define resectability.[1]
- PET/CT may be used in specific situations to better determine cancer recurrence if CT/MRI is inconclusive. These results may allow aggressive interventions (e.g., surgery, radiation, liver directed therapy) to take place with goal of cure, explain elevated or rising CEA level or LFTs with negative conventional imaging and can also be useful to differentiate surgical/radiation scarring from cancer. A systemic review and meta-analysis of 11 studies using PET/CT with elevated CEA and negative CT Chest/Abdomen/Pelvis showed a sensitivity of 94% and specificity of 77% in detection of tumor recurrence.[1,6]

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Colorectal Cancer – Surveillance/Follow-up (ONC-16.4)

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Indication	Medically Necessary Imaging Study
Colon and rectal adenocarcinoma: • Stage I	• No routine advanced imaging
Colon and rectal adenocarcinoma: • Stage II-III	• CT Chest with contrast (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177) after completion of surgery and then annually for 5 years
Colon and rectal adenocarcinoma: • Stage IV or distant metastatic disease (post definitive treatment of all measurable disease or being observed off therapy)	• CT Chest with contrast (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177) every 6 months for 2 years and then annually for 3 years
Measurable metastatic disease on maintenance therapy	Every 3 months for up to 5 years after completion of active treatment: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177)
Rectal cancer treated with transanal excision alone	Any one of the following every 6 months for 5 years: • Endorectal ultrasound (CPT® 76872) • MRI Pelvis without and with contrast (CPT® 72197)
Stage II-III rectal cancer treated with chemoradiation alone (no surgical treatment)	In addition to the above stage-specific surveillance: • MRI Pelvis (CPT® 72197) without and with contrast every 6 months for 3 years

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Indication	Medically Necessary Imaging Study
Pseudomyxoma peritonei	ONE of each of the following, every 3 months for first year, then every 6 months for 4 more years: • CT Chest with (CPT® 71260) or CT Chest without contrast (CPT® 71250) • CT Abdomen and Pelvis with contrast (CPT® 74177) or MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast

Evidence Discussion

- Up to 95% of recurrences occur in the first 5 years after surgery with 80% occurring in the first 3 years, many of which can still be cured supporting the need for CT imaging.
- Given the >90% cure rate with Stage I cancer, routine imaging is not usually indicated.[1]
- Given the recurrence rate between 20%-30% in Stage II-III disease, CT Chest/Abdomen/Pelvis is indicated after completion of surgery (new baseline) and annually for 5 years. More frequent imaging has a lower level of support based on the following trials: FACS, COLOFOL, CEAwatch, and PRODIGE 13.[15]
- For Stage IV cancer status post definitive treatment or being observed off therapy, CT imaging is recommended every 6 months for 2 years then annually for 3 years.[15]
- For Stage IV cancer that is measurable and on maintenance therapy, CT imaging is recommended every 3 months for up to 5 years after completion of active treatment.
- For rectal cancer treated with transanal excision alone, due to higher risk of local recurrence, endorectal ultrasound (EUS) should be performed every 6 months for 5 years with pelvic MRI reserved for abnormal findings on EUS or EUS can't be performed as well as new signs/symptoms concerning for local recurrence.[2]
- Treatment with chemoradiation alone (no surgery) is becoming more common in the setting of rectal cancer in the presence of a complete response to therapy with 5-year survival rates exceeding 80% in several trials. These individuals require additional follow-up studies to include MRI Pelvis every 6 months for 3 years as well as digital rectal exam (DRE)/endoscopy every 3-4 months for 2 years and every 6 months for 3 more years to assess for local recurrence even without signs/symptoms of recurrence.[2]
- Pseudomyxoma peritonei is a condition associated with appendiceal cancer and requires close imaging follow-up due to high risk of recurrence, thus imaging with CT/MRI is indicated every 3 months for year 1 and every 6 months for 4 more years.[1]

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Small Bowel Cancer – Initial Work-up/ Staging (ONC-16.5)

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This section provides imaging guidelines for small bowel adenocarcinoma arising from the duodenum, jejunum, and ileum.

Indication	Medically Necessary Imaging Study
Carcinoma within a polyp that is completely removed	• No advanced imaging
Invasive adenocarcinoma	• CT Chest with contrast (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast ◦ MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197) if CT is inconclusive or cannot be performed

Evidence Discussion

- Cancerous polyps that are completely removed do not require imaging.[1]
- Invasive cancer at any stage requires advanced imaging with CT of Chest/Abdomen/ Pelvis with contrast needed to adequately visualize lung, nodal, and especially liver lesions with MRI of abdomen/pelvis appropriate in the event the CT is inconclusive or cannot be performed.[1]

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Small Bowel Cancer – Restaging/ Recurrence (ONC-16.6)

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Indication	Medically Necessary Imaging Study
Complete resection	• See Surveillance below
Recurrence suspected	• CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast
Unresected primary disease or metastatic disease on chemotherapy	Every 2 cycles of chemotherapy: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177)
Further evaluation of an inconclusive liver lesion seen on CT	• MRI Abdomen without and with contrast (CPT® 74183)
ONE of the following: • Postoperative elevated or rising CEA or LFTs with negative recent conventional imaging • Isolated metastatic lesion(s) on other imaging and individual is a candidate for aggressive surgical resection or other localized treatment to metastasis for curative intent	• PET/CT (CPT® 78815)

Evidence Discussion

- If recurrence is suspected, CT Chest/Abdomen/Pelvis with contrast is the first line of imaging.
- With measurable disease or unresected primary disease on chemotherapy, CT imaging is medically necessary every 2 cycles of treatment to assess response and appropriateness to continue the same treatment or change to new therapy.
- MRI Abdomen is medically necessary for inconclusive liver lesion on CT

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- PET/CT may be used in specific situations to better determine cancer recurrence if CT/MRI is inconclusive. These results may allow aggressive interventions (surgery, radiation, liver directed therapy) to take place with goal of cure and also explain elevated or rising CEA level or LFTs with negative conventional imaging.[3]

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Small Bowel Cancer – Surveillance/ Follow-up (ONC-16.7)

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Indication	Medically Necessary Imaging Study
Stage I-III	• CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast after completion of surgery, and then annually for 5 years
Stage IV - Metastatic disease (post definitive treatment of all measurable disease, or being observed off therapy)	• CT Chest with contrast (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast every 6 months for 2 years and then annually for 3 years
Measurable metastatic disease on maintenance therapy	Every 3 months for up to 5 years after completion of active treatment: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177)

Evidence Discussion

- Stage I, II and III cancers undergo CT Chest/Abdomen/Pelvis at completion of surgery then annually for 5 years, similar to Colorectal guidelines due to lack of data regarding optimal approach.[3,15]
- For Stage IV cancer s/p definitive treatment or being observed off therapy, CT imaging is recommended every 6 months for 2 years then annually for 3 years.
- For Stage IV cancer that is measurable and on maintenance therapy, CT imaging is recommended every 3 months for up to 5 years after completion of active treatment.

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Renal Cell Cancer (RCC) (ONC-17)

Guideline

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Renal Cell Cancer (RCC) – Restaging/Recurrence (ONC-17.3)
Renal Cell Cancer (RCC) – Surveillance (ONC-17.4)
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Renal Cell Cancer (RCC) – General Considerations (ONC-17.0)

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- PET is considered not medically necessary for initial diagnosis, staging or restaging of renal cell cancer.
- A minority of adult individuals with renal cell cancer (RCC) will have translocations in TFE3 or TFEB, which have a different natural history than “adult type” RCC. Individuals of any age with TFE3 or TFEB translocated RCC should be imaged according to guidelines in **Pediatric Renal Cell Carcinoma (RCC) (PEDONC-7.4)** in the Pediatric and Special Populations Oncology Imaging Guidelines.
- Individuals of any age with a Wilms tumor should be imaged according to guidelines in section **Unilateral Wilms Tumor (UWT) (PEDONC-7.2)** or **Bilateral Wilms Tumor (BWT) (PEDONC-7.3)** in the Pediatric and Special Populations Oncology Imaging Guidelines.
- Oncocytoma in individuals of all ages should be imaged according to these guidelines.

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Renal Cell Cancer (RCC) – Suspected/ Diagnosis (ONC-17.1)

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Indication	Medically Necessary Imaging Study
• Solitary renal mass suspicious for renal cell cancer	• See: **Indeterminate Renal Lesion (AB-35.1)** in the Abdomen Imaging Guidelines for evaluation of suspected renal malignancies • CT Chest with contrast with (CPT® 71260) or without contrast (CPT® 71250)

Evidence Discussion

In individuals with RCC or suspicion of RCC, complete staging is typically completed with chest radiography (CXR) or chest CT. CT Chest is preferred.[1,17]

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Renal Cell Cancer (RCC) – Initial Work-up/Staging (ONC-17.2)

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Indication	Medically Necessary Imaging study
All individuals	If not done previously: • CT Chest with (CPT® 71260) or without (CPT® 71250) contrast • CT Abdomen and Pelvis, contrast as requested
ANY of the following: • Extension of tumor into the vena cava by other imaging • Inconclusive findings on CT	• MRI Abdomen without and with contrast (CPT® 74183)
Bone pain	• Bone scan (CPT® 78306) (See: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes)
EITHER of the following: • Signs/symptoms suspicious for brain metastases • Newly diagnosed stage IV/ metastatic RCC	• MRI Brain without and with contrast (CPT® 70553)

Evidence Discussion

American Urological Association (AUA) and the National Comprehensive Cancer Network (NCCN) guidelines stated that pre- and post-contrast enhanced axial imaging, either CT or MRI, is the ideal imaging technique for the diagnosis and staging of clinically localized renal masses. Contrast-enhanced abdominal imaging best characterizes the mass, provides information regarding both the affected and unaffected renal unit, can assess extrarenal tumor spread (venous invasion or regional lymph nodes), and evaluates the adrenal glands and other abdominal organs for visceral metastasis.[1,20,21]

Masses initially diagnosed by ultrasound should be confirmed with pre- and post-contrast enhanced imaging.[1]

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In individuals with RCC or suspicion of RCC, complete staging is typically completed with chest radiography (CXR) or chest CT. Chest CT is preferred.[1] Bone scans should be reserved primarily for individuals with bone pain as the prevalence of osseous metastasis for localized renal cell cancer has been shown to be low in individuals without symptoms suggestive of osseous metastasis. Brain imaging is reserved for individuals with neurologic symptoms, as most individuals with metastasis to the central nervous system are symptomatic, or individuals with newly diagnosed metastatic disease.[1]

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Renal Cell Cancer (RCC) – Restaging/ Recurrence (ONC-17.3)

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Indication	Medically Necessary Imaging Study
Unresectable disease or metastatic disease on systemic therapy	Every 2 cycles of treatment (commonly every 6 to 8 weeks): • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis, contrast as requested (CPT® 74177, CPT® 74178, or CPT® 74176) • CT with contrast of other involved or symptomatic areas
Recurrence suspected	• CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis, contrast as requested (CPT® 74177, CPT® 74178, or CPT® 74176)
EITHER of the following: • Biopsy-proven recurrent/ metastatic disease • Signs or symptoms concerning for brain metastases	• MRI Brain without and with contrast (CPT® 70553)

Evidence Discussion

Individuals presenting with findings suggesting a new renal primary or local recurrence of renal malignancy should undergo metastatic evaluation including chest and abdominal imaging.[1,20,21] The most common sites of distant metastasis include lung, bone, retroperitoneal and mediastinal nodes, liver, brain, or multiple sites.[29,30]

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Renal Cell Cancer (RCC) – Surveillance (ONC-17.4)

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Indication	Medically Necessary Imaging Study
RCC on active surveillance of renal mass <1 cm	ALL of the following, once within 6 months of surveillance initiation and annually thereafter: • CT Abdomen, contrast as requested (CPT® 74170, CPT® 74160, or CPT® 74150) or MRI Abdomen without and with contrast (CPT® 74183) • Chest x-ray ◦ CT Chest with contrast (CPT® 71260) or without contrast (CPT® 71250) is indicated instead of chest x-ray for any of the following: ▪ Known prior thoracic disease ▪ New or worsening pulmonary symptoms ▪ New or worsening chest x-ray findings
RCC on active surveillance of renal mass ≥1 cm	ALL of the following, every 3 months for year 1, every 6 months for years 2 and 3 and annually thereafter: • CT Abdomen, contrast as requested (CPT® 74170, CPT® 74160, or CPT® 74150) OR MRI Abdomen without and with contrast (CPT® 74183) • Chest x-ray ◦ CT Chest with contrast (CPT® 71260) or without contrast (CPT® 71250) is indicated instead of chest x-ray for any of the following: ▪ Known prior thoracic disease ▪ New or worsening pulmonary symptoms ▪ New or worsening chest x-ray findings

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Indication	Medically Necessary Imaging Study
Follow up after post-ablation therapy of RCC	EITHER of the following, at 1 to 3 months, 6 months, and 12 months post-ablation and then annually thereafter: • CT Abdomen, contrast as requested (CPT® 74170), CPT® 74160, or CPT® 74150 or • MRI Abdomen without and with contrast (CPT® 74183) AND Annually for 5 years: • Chest x-ray or CT Chest with contrast (CPT® 71260) or without contrast (CPT® 71250)
Follow up after SBRT	ONE of each of the following, every 3 months for 1 year, every 6 months in year 2, every 9 months in years 3-4, and once in year 5 (to complete 5 years surveillance): • CT Chest with (CPT® 71260) or CT Chest without contrast (CPT® 71250) • CT Abdomen, contrast as requested (CPT® 74170, CPT® 74160, or CPT® 74150) or MRI Abdomen without and with contrast (CPT® 74183)
Stage I RCC, after partial or radical nephrectomy	ONE of each of the following, 3 to 12 months post-resection: • CT Chest with (CPT® 71260) or CT Chest without contrast (CPT® 71250) • CT Abdomen, contrast as requested (CPT® 74170, CPT® 74160, or CPT® 74150) or MRI Abdomen without and with contrast (CPT® 74183) ONE of each of the following, annually for 5 years: • CT Chest with (CPT® 71260) or CT Chest without (CPT® 71250) contrast • MRI Abdomen without and with contrast (CPT® 74183) or CT Abdomen, contrast as requested (CPT® 74170, CPT® 74160, or CPT® 74150)

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Indication	Medically Necessary Imaging Study
Stage II RCC, post-nephrectomy	ONE of each of the following, 3 to 6 months post-resection: • CT Chest with (CPT® 71260) or CT Chest without (CPT® 71250) contrast • CT Abdomen, contrast as requested (CPT® 74170, CPT® 74160, or CPT® 74150), or CT Abdomen and Pelvis, contrast as requested (CPT® 74177, CPT® 74176, or CPT® 74178), or MRI Abdomen without and with contrast (CPT® 74183) +/- MRI Pelvis without and with contrast (CPT® 72197) ONE of each of the following, every 6 months for 2 years, then annually until year 5: • CT Chest with (CPT® 71260) or CT Chest without (CPT® 71250) contrast • MRI Abdomen without and with contrast (CPT® 74183) +/- MRI Pelvis without and with contrast (CPT® 72197), or CT Abdomen, contrast as requested (CPT® 74170, CPT® 74160, or CPT® 74150), or CT Abdomen and Pelvis, contrast as requested (CPT® 74177, CPT® 74176, CPT® 74178)
Stage III RCC, post-nephrectomy	ONE of each of the following, 3 to 6 months post-resection: • CT Chest with (CPT® 71260) or CT Chest without (CPT® 71250) contrast • CT Abdomen, contrast as requested (CPT® 74170, CPT® 74160, or CPT® 74150), or CT Abdomen and Pelvis, contrast as requested (CPT® 74177, CPT® 74176, or CPT® 74178), or MRI Abdomen without and with contrast (CPT® 74183) +/- MRI Pelvis without and with contrast (CPT® 72197) ONE of each of the following, every 3 months for 3 years, then annually to year 5: • CT Chest with (CPT® 71260) or CT Chest without (CPT® 71250) contrast • CT Abdomen, contrast as requested (CPT® 74170, CPT® 74160, or CPT® 74150), or CT Abdomen and Pelvis, contrast as request (CPT® 74177, CPT® 74176, CPT® 74178), or MRI Abdomen without and with contrast (CPT® 74183)

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Indication	Medically Necessary Imaging Study
Stage IV/metastatic disease on maintenance therapy or being observed off therapy	ONE of each of the following, every 3 months for up to 5 years after completion of active treatment: • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) • CT Abdomen, contrast as requested (CPT® 74170, CPT® 74160, or CPT® 74150), or CT Abdomen and Pelvis contrast as requested (CPT® 74177, CPT® 74176, or CPT® 74178), or MRI Abdomen without and with contrast (CPT® 74183) +/- MRI Pelvis without and with contrast (CPT® 72197)

Evidence Discussion

Active surveillance Stage T1a:

Active surveillance entails serial abdominal imaging in order to study the growth rate of the tumor and it is recommended that abdominal imaging (CT or MRI with contrast) within 6 months from initiation of active surveillance; subsequent imaging (with CT, MRI, or ultrasound [US]) may be performed annually thereafter. CT and MRI have both been found to accurately predict pathologic tumor size in a retrospective analysis.[23] Therefore, best clinical judgment should be used in choosing the imaging modality. A chest x-ray or chest CT at baseline and annually as clinically indicated to assess for pulmonary metastases. Repeat chest imaging can be considered if intervention is being contemplated.[1]

Follow up after ablative therapy for Stage T1a:

An abdominal imaging, either CT or MRI with and without IV contrast (unless otherwise contraindicated), at 1 through 6 months to assess treatment response, followed by annual abdominal CT or MRI (preferred) for 5 years or longer as clinically indicated. If the individual cannot receive IV contrast, MRI is preferred.[1]

Follow up after partial or radical nephrectomy for Stages 1-2:

Stage I RCC, it is recommended that abdominal CT or MRI (preferred) within 3 to 12 months following renal surgery, then annually for up to 5 years or longer as clinically indicated. For individuals with stage II RCC, it is recommended to increase in abdominal imaging frequency, with baseline abdominal CT or MRI (preferred) every 6 months for 2 years, then annually for up to 5 years or longer, as clinically indicated.[1]

It is also recommended that yearly chest x-ray or CT for at least 5 years and as clinically indicated thereafter.[1]

Follow up for individuals with Stage 3 RCC:

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It is recommended to obtain a baseline abdominal CT or MRI within 3 to 6 months following surgery, followed by CT, MRI (preferred), or US every 3 to 6 months for at least 3 years, and annually thereafter for up to 5 years.[1]

A baseline chest CT within 3 to 6 months following surgery is also recommended along with continued imaging (CT preferred) every 3 to 6 months for at least 3 years, and annually thereafter for up to 5 years.[1]

CT is the preferred modality for those with a high risk of recurrence.

Follow up for an individual with relapse or unresectable disease or Stage 4 RCC:

It is recommended to obtain chest, abdominal and pelvic imaging at baseline and then as clinically indicated based on clinical status, and therapeutic schedule.[1]

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Transitional Cell Cancer (ONC-18)

Guideline

Transitional Cell Cancer – General Considerations (ONC-18.0)
Transitional Cell Cancer – Suspected/Diagnosis (ONC-18.1)
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Transitional Cell Cancer – Surveillance/Follow-up (ONC-18.4)
References (ONC-18)

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Transitional Cell Cancer – General Considerations (ONC-18.0)

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- Transitional cell cancers can include: tumors of the bladder, ureters, prostate, urethra, or renal pelvis. For primary cancer of the kidney, see: **Renal Cell Cancer (RCC) (ONC-17)**.
- Most common histology of bladder cancer is transitional cell (TCC) or urothelial carcinoma (UCC). Rare histologies include adenocarcinoma, squamous cell (imaged according to **Transitional Cell Cancer (ONC-18)**), or small cell (imaged according to **Extrathoracic Small Cell and Large Cell Neuroendocrine Tumors (ONC-31.8)**).
- Urachal cancer is rare type of bladder cancer; the most common histology is adenocarcinoma. These are imaged according to muscle invasive bladder cancer.
- PET not routinely indicated in transitional cell cancer with exception noted below in **Transitional Cell Cancer – Initial Work-up/Staging (ONC-18.2)**.

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Transitional Cell Cancer – Suspected/ Diagnosis (ONC-18.1)

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- See: **Hematuria and Hydronephrosis (AB-39)** in the Abdomen Imaging Guidelines for evaluation of suspected transitional cell malignancies.

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Transitional Cell Cancer – Initial Work-up/Staging (ONC-18.2)

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Indication	Medically necessary Imaging Study
All individuals	ONE of the following: • CT Abdomen and Pelvis without and with contrast (CPT® 74178) ◦ MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast if contraindication to CT contrast • CT Abdomen and Pelvis without contrast (CPT® 74176) with retrograde pyelogram or renal ultrasound (CPT® 76770 or CPT® 76775) in individuals who cannot receive either CT or MRI contrast
Sessile or high-grade tumors	In addition to the imaging above, if not already performed: • MRI Pelvis without and with contrast (CPT® 72197)
ANY of the following: • Muscle invasive bladder carcinoma • Urethral carcinoma • Urothelial carcinoma of the prostate	• CT Chest without (CPT® 71250) or with (CPT® 71260) contrast
Individuals without metastatic disease, when requested by operating surgeon for operative planning	• CT with contrast or MRI without and with contrast of all operative sites

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Indication	Medically necessary Imaging Study
Evaluation of suspected bone metastasis: • Individuals with symptoms of bone metastasis • Laboratory indicators of bone metastasis • Individuals with muscle invasive disease • Suspected sites of extra-osseous metastatic disease	Any ONE of the following: • Bone scan (CPT® 78306) (see: **Nuclear Medicine (NM) Imaging in Oncology [ONC-1.3]** for additional bone scan codes) • MRI without and with contrast of areas of suspected involvement • FDG PET/CT (CPT® 78815)
To evaluate inconclusive findings on conventional imaging	• PET/CT (CPT® 78815)
Suspected brain metastases	See: **Brain Metastases (ONC-31.3)**

Evidence Discussion

Initial staging of non-muscle invasive bladder cancer (NMIBC)

A clinician should perform upper tract imaging as a component of the initial evaluation of an individual with bladder cancer. NCCN guidelines recommend CT urography CTU (CT of the abdomen and pelvis without and with IV contrast with excretory imaging), which is an imaging study that is tailored to improve visualization of both the upper and lower urinary tracts. CT scan can require a significant dose of ionizing radiation but the speed of image acquisition reduces the potential for motion artifact.

MR urography (MRU) may be appropriate, especially in an individual with poor renal function or iodinated contrast allergy but with GFR >30 and no acute renal failure. MRU can be degraded due to motion artifact, but there is no ionizing radiation with this imaging modality.

CTU and MRU allow for comprehensive evaluation of the genitourinary tract, as well as assessment of retroperitoneal and pelvic lymph nodes.

Renal ultrasound (US) or CT without contrast may be utilized in conjunction with retrograde ureteropyelography in individuals who cannot receive either iodinated or gadolinium-based contrast material. Ultrasound requires no ionizing radiation, but is not sufficient for evaluation alone, and must be combined with either retrograde ureteropyelography or ureteroscopy to completely evaluate the upper urinary tract.[1]

NCCN guidelines stated that chest imaging may not be necessary in the initial staging of non-invasive disease, as the risk of chest metastasis in individuals with TA or T1 NMBIC is low.[1,8]

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FDG PET/CT is not recommended to delineate the anatomy of the upper urinary tract as it does not provide detailed imaging of the bladder. Thus, it is reserved as a problem-solving tool when other imaging studies are inconclusive.[1]

Initial staging of non-metastatic muscle-invasive bladder cancer (MIBC)

Prior to muscle-invasive bladder cancer management, clinicians should perform a complete staging evaluation, including imaging of the chest and cross-sectional imaging of the abdomen and pelvis with intravenous contrast if not contraindicated. Laboratory evaluation should include a comprehensive metabolic panel (complete blood count, liver function tests, alkaline phosphatase, and renal function).

All individuals with MIBC require imaging of the thorax. Chest radiography is an effective screening exam. Any abnormality should be followed up with a CT exam.

For sessile or high-grade tumors, it is recommended that MRI Pelvis be performed in addition to CTU for local staging.[1]

NCCN indicated that bone imaging is medically necessary if there are clinical indications of bone metastases or in individuals with muscle-invasive disease.[1]

FDG PET/CT is not recommended to delineate the anatomy of the upper urinary tract as it does not provide detailed imaging of the bladder. Thus, it is reserved as a problem-solving tool when other imaging studies are inconclusive.

Initial staging of Urothelial Carcinoma of the prostate/primary carcinoma of the urethra

Initial work up is similar to non-metastatic muscle invasive bladder cancer and should include Chest CT, CTU or MRU.

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Transitional Cell Cancer – Restaging/ Recurrence (ONC-18.3)

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Indication	Medically Necessary Imaging Study
After definitive surgery	• CT Abdomen and Pelvis with contrast (CPT® 74177) or CT Abdomen and Pelvis without and with contrast (CPT® 74178) for post-operative baseline
Recurrence suspicion	• CT Abdomen and Pelvis with contrast (CPT® 74177) or with and without contrast (CPT® 74178) • CT Chest with contrast (CPT® 71260) for ANY of the following: ◦ Known prior thoracic disease ◦ New or worsening pulmonary symptoms ◦ New or worsening chest x-ray findings ◦ Known prior or suspected muscle invasive disease
After neoadjuvant therapy and before resection	• CT Chest with contrast (CPT® 71260) and CT Urogram (CPT® 74178)
Monitoring therapy for metastatic disease	Every 2 cycles of therapy: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Chest with contrast (CPT® 71260) for ANY of the following: ◦ Known prior thoracic disease ◦ New or worsening pulmonary symptoms ◦ New or worsening chest x-ray findings
To evaluate inconclusive findings on conventional imaging	• PET/CT (CPT® 78815)

Evidence Discussion

Individuals presenting with findings suggesting a new primary or local recurrence of malignancy should undergo metastatic evaluation including abdominal and pelvic

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imaging. The most common sites for metastasis include lymph nodes, bone, lung, liver, and peritoneum.[10] The recommended imaging for restaging of suspected recurrence mirrors that which is performed in initial staging.[1,6]

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Transitional Cell Cancer – Surveillance/ Follow-up (ONC-18.4)

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Indication	Medically Necessary Imaging Study
ANY of the following: • Papillary urothelial neoplasm of low malignant potential • Low risk lesions ◦ Solitary Ta lesions ≤3cm • Intermediate risk lesions ◦ Low-grade >3cm ◦ Low-grade multifocal ◦ T1 lesions ◦ High-grade solitary Ta ≤3cm	One-time baseline imaging at the end of therapy: • CT Urogram (CPT® 74178) or MR Urogram (CPT® 74183 and CPT® 72197) • Further advanced imaging is not routinely medically necessary for surveillance
ANY of the following high-risk non-muscle invasive transitional cell carcinoma of the bladder or upper tracts: • Multifocal high-grade lesions • High-grade lesions >3 cm • Superficial and minimally invasive (Tis and T1) • BCG unresponsive • Lymphovascular invasion • Prostatic urethral invasion	• CT Urogram (CPT® 74178) or MR Urogram (CPT® 74183 and CPT® 72197) (imaging as performed at initial staging) every 1-2 years for 10 years
Non-muscle-invasive transitional carcinoma of the bladder treated with cystectomy	• CT Urogram (CPT® 74178) or MR Urogram (CPT® 74183 and CPT® 72197) (imaging as performed at initial staging) at 3 and 12 months post-cystectomy, and then annually for years 2-5

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Indication	Medically Necessary Imaging Study
Muscle invasive lower and upper genitourinary tumors treated with cystectomy, nephrectomy, or chemoradiation	Every 3-6 months for 2 years, then annually for 3 more years: • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250), and CT Abdomen and Pelvis with contrast (CPT® 74177) or without and with contrast (CPT® 74178) OR • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250), and MR Urogram (CPT® 74183 and CPT® 72197)
Measurable metastatic disease on maintenance therapy or being monitored off therapy	Every 3 months for up to 5 years after completion of active treatment: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177), CT Urogram (CPT® 74178), or MR Urogram (CPT® 74183 and CPT® 72197) (imaging as performed at initial staging)
Urethral cancers (high-risk T1 or greater) and urothelial carcinoma of the prostate	Every 3-6 months for 2 years, then annually: • CT Abdomen and Pelvis with contrast (CPT® 74177) or without and with contrast (CPT® 74178) OR • MR Urogram (CPT® 74183 and CPT® 72197) AND • Chest x-ray ◦ CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) for any of the following: ▪ Signs/symptoms of pulmonary disease ▪ Abnormal chest x-ray ▪ Prior involvement of the chest

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Evidence Discussion

Surveillance of non-muscle invasive bladder cancer[1,7]

In an asymptomatic individual with a history of low-risk NMIBC a clinician should not perform routine surveillance upper tract imaging, after the initial baseline.

For an intermediate or high-risk individual, a clinician should consider performing surveillance upper tract imaging at 1-2 year intervals. Initially obtain imaging at 12 months, then every 1-2 years up to 10 years. CT urography (CTU), MRU, or retrograde ureteropyelography with non-contrast CT or US or ureteroscopy with a non-contrast CT or US.

Routine chest imaging is not appropriate for individuals with NMBIC unless an abnormality is identified with chest radiography.

Surveillance of non-metastatic muscle-invasive bladder cancer[1,7]

Clinicians should obtain chest imaging and cross-sectional imaging of the abdomen and pelvis with CT or MRI at 6-12 month intervals for 2-3 years and then may continue annually.

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References (ONC-18)

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Prostate Cancer (ONC-19)

Guideline

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Prostate Cancer – General Considerations (ONC-19.0)

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- Prostate cancer screening begins at age 45 for individuals at average risk of prostate cancer. However, individuals at high-risk may begin screening at age 40. High-risk features include:
  - African ancestry
  - germline mutations (BRCA1 or 2, HOXB13, ATM, CHEK2, or mismatch repair genes (MLH1, MSH2, MSH6, PMS2) that increase the risk of prostate cancer
  - family history of first or second-degree relative with prostate, male breast, colorectal, pancreatic, endometrial or female breast cancer at age <45 years
- Treatment of benign prostatic hyperplasia with 5-alfa reductase inhibitors (such as finasteride and dutasteride) can falsely reduce the measured PSA levels by 50%. Thus, the reported PSA level should be doubled when prostate cancer is suspected in individuals on these medications.
- Individuals with high-risk adverse clinical and pathological factors may benefit from a more aggressive diagnostic and therapeutic approach at the time of relapse after initial treatment. These factors include pre-treatment Gleason score of ≥8, pre-treatment clinical stage of cT3b or higher, positive surgical margins, post-treatment PSA doubling time of <3 months, and an interval to biochemical failure of <3 years after initial treatment.
- PET/CT scans using ^{18}F-FDG radiotracer are not medically necessary for evaluation of prostate cancer.
- ^{11}C Choline, ^{18}F-Fluciclovine (AXUMIN®), and PSMA-specific radiopharmaceuticals have recently gained FDA approval for evaluation of prostate cancer. Optimal detection rates for these radiotracers vary greatly with PSA levels. False positive rate is high and histological confirmation of positive sites is recommended.
- PSMA-specific PET radiopharmaceuticals that are currently FDA-approved and indicated in prostate cancer are: ^{68}Ga PSMA-11 (UCSF & UCLA), ^{18}F Piflufolastat (Pylarify®), ^{18}F Flotufolastat (Posluma®), and ^{68}Ga Gozetotide (Illuccix® and Locametz®).
- While early detection of low-volume recurrence after treatment of prostate cancer using PET/CT scans may influence therapeutic decisions, there is lack of evidence that this approach has any meaningful impact on overall survival.
- As high-intensity focused ultrasound prostate ablation is considered investigational and experimental at this time, and advanced imaging for treatment planning and/or

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surveillance of high intensity focused ultrasound prostate ablation is not medically necessary.
- MR Spectroscopy (CPT® 76390) is considered not medically necessary in the evaluation of prostate cancer at this time.
- As laser prostate ablation is considered investigational and experimental at this time, advanced imaging for treatment planning and/or surveillance of laser prostate ablation is not medically necessary.
- Monitoring an elevated prostate-specific antigen level (PSA) with serial MRI is not medically necessary for suspected prostate cancer.
- Requests for imaging based on PSA must provide a recent PSA.

ISUP Prostate Cancer Grade Groups

Grade Group	Gleason Score	Gleason Pattern
1	≤6	≤3+3
2	7	3+4
3	7	4+3
4	8	4+4, 3+5, 5+3
5	9 or 10	4+5, 5+4, or 5+5

NCCN Initial Risk Stratification
- Very Low Risk
  - ALL of the following features are present:
    - Tumor not clinically palpable, but present on one or both lobes on biopsy (cT1a, cT1b, or cT1c)
    - PSA (ng/mL) <10
    - Gleason Grade Group = 1
    - <3 prostate biopsy cores positive, ≤50% cancer in each core
    - PSA Density <0.15 ng/mL/g
- Low Risk
  - ALL of the following features are present but does not qualify for very low risk:
    - Clinical T Stage = cT1-cT2a (palpable tumor limited to ≤1/2 of one side)
    - PSA (ng/mL) <10
    - Gleason Grade Group = 1
- Intermediate Risk

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  - No "high-risk" or "very high-risk" features and one or more of the following intermediate risk factors (IRFs):
    - cT2b-cT2c
    - Grade group 2 or 3
    - PSA 10-20 ng/mL
  - Favorable Intermediate Risk
    - ALL of the following features must be present:
      - Only 1 IRF
      - Gleason Grade Group = 1 or 2
      - <50% biopsy cores positive (e.g., <6 of 12 cores)
  - Unfavorable Intermediate Risk
    - One or more of the following must be present:
      - 2 or 3 IRFs
      - Gleason grade group = 3
      - ≥50% biopsy cores positive (e.g., ≥6 of 12 cores)
- High-Risk
  - ONE or more of the following high-risk features is present:
    - Clinical T Stage = cT3-cT4
    - PSA (ng/mL) >20
    - Gleason Grade Group = 4 or 5
- Very High-Risk
  - At least TWO of the following features is present:
    - Clinical T stage = cT3-cT4 (extension into the seminal vesicles or invasion into adjacent structures)
    - Primary Gleason Pattern = 5
    - Gleason Grade Group = 4 or 5
    - PSA (ng/mL) >40

3D Rendering of MRI for MRI / Ultrasound Fusion Biopsy:

- When specific target lesion(s) is (are) detected on multi-parametric MRI (mpMRI) prostate and classified as PIRADS 4 or 5, 3D Rendering (CPT® 76377) to generate prostate segmentation data image set for target identification on MRI/Transrectal ultrasound (TRUS) fusion biopsy is medically necessary as:
  - a subsequent separate standalone request; or
  - a retrospective request for medical necessity
- For MRI/TRUS fusion biopsy of a PIRADS 1-3 lesion, approval of 3D rendering at independent workstation (CPT® 76376 or CPT® 76377) can be considered on a case-by-case basis.

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- If there is no target lesion identified on MRI, then 3D rendering and MRI/TRUS fusion biopsy is generally not medically necessary.
- The 3D rendering for the TRUS component of the fusion is a part of the UroNav Fusion Equipment Software and an additional 3D code CPT® 76376 or CPT® 76377 is not medically necessary.

Evidence Discussion

Screening can begin as early as age 40 for high-risk individuals (Black/African-American identity, certain germline mutations, or concerning family history) and 45 for individuals with average risk. Those with a first-degree relative diagnosed at age less than 60 years have a more than 2-fold increase in likelihood of prostate cancer diagnosis. Individuals with African ancestry have a 60% higher incidence of prostate cancer. Individuals with high-risk adverse clinical and pathologic factors may benefit from a more aggressive diagnostic and therapeutic approach at the time of relapse after initial treatment.[2]

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Suspected Prostate Cancer (ONC-19.1)

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- MR guidance for needle placement (CPT® 77021) is not medically necessary for prostate biopsy.

Indication	Medically Necessary Imaging Study
ANY of the following: • Age 40-75 years with PSA >3 ng/ml or very suspicious DRE and ONE of the following high-risk features: ◦ African ancestry ◦ Germline mutations that increase the risk of prostate cancer ◦ Family history of first- or second-degree relative with prostate, male breast, pancreatic, or ovarian cancer ◦ Family history of first- or second-degree relative diagnosed at age ≤45 years with female breast cancer ◦ Family history of first- or second-degree relative diagnosed at age ≤50 years with colorectal or endometrial cancer • Age 45-75 years and ONE of the following: ◦ PSA >3 ng/ml ◦ Very suspicious DRE • Age >75 years and ONE of the following: ◦ PSA ≥4 ng/ml ◦ Very suspicious DRE • At least one negative/non-diagnostic TRUS biopsy and ANY of the following: ◦ Rising PSA ◦ Abnormal DRE ◦ Need for confirmatory MR/US fusion biopsy	ANY of the following: • Transrectal ultrasound (CPT® 76872) • TRUS-guided biopsy (CPT® 76942) • MRI/US fusion biopsy (CPT® 76942) • If results of MRI will be used to determine the need for, and subsequently perform, MR fusion biopsy: ◦ MRI Pelvis without and with contrast (CPT® 72197) OR ◦ MRI Pelvis without contrast (CPT® 72195)

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Indication	Medically Necessary Imaging Study
• PIRADS 4 or 5 lesion identified on recent diagnostic MRI Pelvis (CPT® 72195 or CPT® 72197) and planning for biopsy to be done by MRI/TRUS fusion technique	• 3D Rendering (CPT® 76376 or CPT® 76377)
ANY of the following: • Multifocal (2 or more lesions) high-grade prostatic intraepithelial neoplasia (PIN) • Atypia on biopsy	• Extended pattern re-biopsy within 6 months by TRUS-guided biopsy (CPT® 76942)
• Solitary PIN (1 lesion)	ONE of the following, to be repeated in one year: • MRI Pelvis without contrast (CPT® 72195) • MRI Pelvis without and with contrast (CPT® 72197) • MRI/US fusion biopsy (CPT® 76942 or 76872) ◦ These codes are medically necessary in addition to MR Pelvis codes above, if requested
In office, transperineal, MRI guided biopsy without US fusion (i.e., ProMaxo)	Diagnostic MRI code (CPT® 77021) is not medically necessary in conjunction with procedure codes (see: **CT-, MR-, or US-Guided Procedures (Preface-4.2)**)

Evidence Discussion

Based on the high-risk factors outlined above along with age, digital rectal exam (DRE) findings and PSA level, further imaging work-up may be medically necessary to include transrectal ultrasound with or without biopsy, MRI of the pelvis without and/or with contrast as well as MRI/US fusion biopsy is indicated. These interventions will help dictate the appropriate therapy for each individual diagnosed with prostate cancer.[1]

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Prostate Cancer – Initial Work-up/ Staging (ONC-19.2)

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Indication	Medically Necessary Imaging Study
Localized prostate cancer with any of the following risk groups (see: **ONC-19.0** for definition of risk groups): • Very low risk • Low risk • Favorable intermediate risk	Advanced imaging is not routinely medically necessary for initial staging If not already performed prior to biopsy, MRI Pelvis without and with contrast (CPT® 72197) is appropriate for any of the following: • Prior to planned treatment (surgery and/or radiation therapy) • To establish candidacy for active surveillance
Localized prostate cancer with any of the following risk groups (see: **ONC-19.0** for definition of risk groups): • Unfavorable intermediate risk • High-risk • Very high-risk	Any ONE of the following combinations, not all (may be obtained in addition to mpMRI prostate): • CT Chest with contrast (CPT® 71260), CT Abdomen and Pelvis with contrast (CPT® 74177), and Bone scan (CPT® 78306) • CT Chest with contrast (CPT® 71260), CT Abdomen with contrast (CPT® 74160), MRI Pelvis without and with contrast (CPT® 72197) if not previously performed, and Bone scan (CPT® 78306) • PSMA PET/CT scan (CPT® 78815 or CPT® 78816) using any one of the following radiotracers: ◦ ^{68}Ga-PSMA-11 ◦ ^{18}F Piflufolastat (Pylarify®) ◦ ^{68}Ga Gozetotide (Illuccix® and Locametz®) ◦ ^{18}F Flotufolastat (Posluma®)

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Indication	Medically Necessary Imaging Study
To confirm oligo- or low volume metastatic prostate cancer suspected on conventional imaging in individuals with biopsy-proven prostate cancer	• PSMA PET/CT (CPT® 78815 or CPT® 78816) or PSMA PET/MRI (CPT® 78813 and CPT® 76498) with any of the following radiotracers: ◦ ^{68}Ga-PSMA-11 ◦ ^{18}F Piflufolastat (Pylarify®) ◦ ^{18}F Flotufolastat (Posluma®) ◦ ^{68}Ga Gozetotide (Illuccix® and Locametz®)
Known diffuse metastatic prostate cancer (including prior to prostate biopsy)	Any ONE of the following combinations, not all: • CT Chest with contrast (CPT® 71260), CT Abdomen and Pelvis with contrast (CPT® 74177), and Bone scan (CPT® 78306) • CT Chest with contrast (CPT® 71260), CT Abdomen with contrast (CPT® 74160), MRI Pelvis without and with contrast (CPT® 72197) if not previously performed, and Bone scan (CPT® 78306)
Inconclusive bone scan	Any ONE of the following: • CT with contrast of involved body site • MRI without and with contrast of involved body site • PET/CT (CPT® 78815 or CPT® 78816) or PET/MRI (CPT® 78813 and CPT® 76498) using any one of the following radiotracers: ◦ ^{18}F Fluciclovine ◦ ^{11}C Choline ◦ ^{68}Ga-PSMA-11 ◦ ^{18}F Piflufolastat (Pylarify®) ◦ ^{18}F Flotufolastat (Posluma®) ◦ ^{68}Ga Gozetotide (Illuccix® and Locametz®) ◦ ^{18}F sodium fluoride

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Evidence Discussion

Risk stratification uses a minimum of stage, Gleason grade, and PSA to assign individuals to risk groups that in turn help select the imaging options and predict the probability of biochemical recurrence after definitive local therapy. The current prostate cancer grading system was adopted from the ISUP 2014 consensus conference with the goal to limit overtreatment. The grading system is divided into 6 risk groups.

The goal of imaging is to detect and characterize disease in order to guide disease management. Very low risk, low risk, and favorable intermediate risk does not routinely require advanced imaging. NCCN stated that "conventional bone scans are rarely positive in asymptomatic individuals with PSA <10 ng/mL".[1] Very low risk, low risk, and favorable intermediate risk groups have very low risk of positive bone scan or CT scan.[1]

Unfavorable intermediate risk, high-risk, and very high-risk do require imaging that can be a combination of CT/MRI Pelvis or PSMA PET using specific radiotracers. In individuals with known or suspected metastatic disease, CT Chest, Abdomen, and Pelvis along with bone scan are indicated. MRI Pelvis is an acceptable choice in lieu of CT Pelvis due to MRI's ability to provide detailed soft tissue characterization and contrast. NCCN supported bone imaging for those at high risk for skeletal metastases[1]

For inconclusive bone findings, NCCN stated that additional imaging using CT, MRI, PSMA-PET/CT or PSMA-PET/MRI, or PET/CT or PET/MRI with F-18 sodium fluoride, C-11 choline, or F-18 fluciclovine can be considered. For conventional imaging suggesting oligo- or low-volume metastatic disease, PET/CT using specific radiotracers can be performed to confirm the individual is a candidate for localized treatment. F18-FDG PET/CT scans are considered not medically necessary for evaluation of prostate cancer because, per NCCN, there is a lack of data surrounding the use of this radiotracer in individuals with prostate cancer. Other radiotracers (C11 choline, F18-Fluciclovine, PSMA-specific) are FDA approved and have influenced treatment planning but the impact on long-term survival remains to be studied. However, data does indicate that PSMA-PET has a high sensitivity for metastatic disease and small-volume disease compared to conventional imaging and therefore it has become a useful tool for the evaluation of individuals with prostate cancer.[1]

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Prostate Cancer – Restaging/Recurrence (ONC-19.3)

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Indication	Medically Necessary Imaging Study
For ANY of the following: • Obvious progression by DRE with plans for prostatectomy or radiation therapy • Repeat TRUS biopsy for rising PSA shows progression to a higher Gleason's score with plans for prostatectomy or radiation therapy • Inconclusive findings on CT scan	• MRI Pelvis without and with contrast (CPT® 72197)
Non-metastatic prostate cancer previously treated with ablation, hormonal therapy, or chemotherapy **and** any one of the following: • Clinical suspicion of relapse/recurrence • Palpable anastomotic recurrence • PSA rises above post-treatment baseline to >0.2 ng/mL on two consecutive measurements	Any ONE of the following combinations: • CT Chest with contrast (CPT® 71260), CT Abdomen and Pelvis with contrast (CPT® 74177), and Bone scan (CPT® 78306) (see: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes) • CT Chest with contrast (CPT® 71260), CT Abdomen with contrast (CPT® 74160), MRI Pelvis without and with contrast (CPT® 72197), and Bone scan (CPT® 78306) (see: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes)

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Indication	Medically Necessary Imaging Study
Non-metastatic prostate cancer previously treated with prostatectomy and **all** of the following are met: • Persistent detectable PSA after prostatectomy, or • Undetectable PSA that subsequently becomes detectable with two consecutive increases in PSA (to any amount), or • Any increase in PSA to 0.1 ng/mL or higher AND: • Individual is a candidate for salvage local therapy	Any ONE of the following: • PSMA PET/CT scan (CPT® 78815 or CPT® 78816) or PET/MRI (CPT® 78813 and CPT® 76498) with any of the following radiotracers: ◦ ^{68}Ga-PSMA-11 ◦ ^{18}F Piflufolastat (Pylarify®) ◦ ^{18}F Flotufolastat (Posluma®) ◦ ^{68}Ga Gozetotide (Illuccix® and Locametz®) • CT Chest with contrast (CPT® 71260), CT Abdomen and Pelvis with contrast (CPT® 74177), and Bone scan (CPT® 78306) • CT Chest with contrast (CPT® 71260), CT Abdomen with contrast (CPT® 74160), MRI Pelvis without and with contrast (CPT® 72197), and Bone scan (CPT® 78306) (see: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes)

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Indication	Medically Necessary Imaging Study
Non-metastatic prostate cancer previously treated with radiation therapy and **both** of the following are met: • Two consecutive increases in PSA above nadir AND • Individual is a candidate for salvage local therapy	Any ONE of the following: • PSMA PET/CT scan (CPT® 78815 or CPT® 78816) or PET/MRI (CPT® 78813 and CPT® 76498) with any of the following radiotracers: ◦ ^{68}Ga-PSMA-11 ◦ ^{18}F Piflufolastat (Pylarify®) ◦ ^{18}F Flotufolastat (Posluma®) ◦ ^{68}Ga Gozetotide (Illuccix® and Locametz®) • CT Chest with contrast (CPT® 71260), CT Abdomen and Pelvis with contrast (CPT® 74177), and Bone scan (CPT® 78306) • CT Chest with contrast (CPT® 71260), CT Abdomen with contrast (CPT® 74160), MRI Pelvis without and with contrast (CPT® 72197), and Bone scan (CPT® 78306) (see: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes)
Non-metastatic prostate cancer previously treated with prostatectomy or radiation therapy, and **all** of the following are met: • PSA rises on two consecutive measurements above post-treatment baseline **and** • PSA ≥1 ng/mL **and** • Recent CT scan and bone scan are negative for metastatic disease **and** • Individual is a candidate for salvage local therapy	• PET/CT scan (CPT® 78815 or CPT® 78816) using any **ONE** of the following radiotracers: ◦ ^{18}F-Fluciclovine ◦ ^{11}C Choline

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Indication	Medically Necessary Imaging Study
Suspected progression of known metastatic disease based on: • New or worsening signs/symptoms • Rising PSA levels	• CT Chest with contrast (CPT® 71260), CT Abdomen and Pelvis with contrast (CPT® 74177), and Bone scan (CPT® 78306) (see: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes) • CT with contrast of any involved or symptomatic body part
Metastatic prostate cancer receiving treatment with chemotherapy or Pluvicto®	One of the following combinations, every 2 cycles (6 to 8 weeks), while on chemotherapy: • CT Abdomen and Pelvis with contrast (CPT® 74177) and CT scan with contrast of any involved body part OR • CT Abdomen with contrast (CPT® 74160), MRI Pelvis without and with contrast (CPT® 72197) AND, every 3-6 months: • Bone scan (CPT® 78306) (see: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes)

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Indication	Medically Necessary Imaging Study
Metastatic prostate cancer receiving anti-androgen therapy	One of the following combinations, every 3 months, while on anti-androgen therapy: • CT Abdomen and Pelvis with contrast (CPT® 74177) and CT scan of any involved body part OR • CT Abdomen with contrast (CPT® 74160), MRI Pelvis without and with contrast (CPT® 72197) AND, every 3-6 months: • Bone scan (CPT® 78306) (see: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes)
Previously treated metastatic prostate cancer progressed on conventional imaging and being considered for ^{177}Lu-PSMA-617 (Pluvicto®) treatment[31, 32]	• PSMA PET/CT scan (CPT® 78815 or CPT® 78816) with one of the following agents: ◦ ^{68}Ga PSMA-11 ◦ ^{18}F Piflufolastat (Pylarify®) ◦ ^{68}Ga Gozetotide (Illuccix® and Locametz®) ◦ ^{18}F Flotufolastat (Posluma®)
Prior to start of Xofigo® (Radium-223) therapy	• ONE time CT Chest, Abdomen, and Pelvis with contrast (CPT® 71260 and CPT® 74177)

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Indication	Medically Necessary Imaging Study
Inconclusive bone scan	Any ONE of the following: • CT with contrast of involved body site • MRI without and with contrast of involved body site • PET/CT (CPT® 78815 or CPT® 78816) or PET/MRI (CPT® 78813 and CPT® 76498) using any one of the following radiotracers: ◦ ^{18}F Fluciclovine ◦ ^{11}C Choline ◦ ^{68}Ga-PSMA-11 ◦ ^{18}F Piflufolastat (Pylarify®) ◦ ^{18}F Flotufolastat (Posluma®) ◦ ^{68}Ga Gozetotide (Illuccix® and Locametz®) ◦ ^{18}F sodium fluoride
Conventional imaging studies (CT and bone scan) suggests oligo- or low volume metastatic disease that needs further confirmation	• PET/CT scan (CPT® 78815 or CPT® 78816) using any one of the following radiotracers: ◦ ^{18}F Fluciclovine ◦ ^{11}C Choline ◦ ^{68}Ga-PSMA-11 ◦ ^{18}F Piflufolastat (Pylarify®) ◦ ^{68}Ga Gozetotide (Illuccix® and Locametz®) ◦ ^{18}F Flotufolastat (Posluma®)

Evidence Discussion

The use of PSMA PET radiotracers has been shown to impact treatment planning but more research is needed on the impact to long-term outcomes. However, the benefit to individuals of initiating treatment earlier for recurrent disease detected on PSMA PET outweighs the disadvantages of possible false-positives. For non-metastatic prostate cancer previously treated with prostatectomy, NCCN stated that PET can be used without prerequisite conventional imaging for suspected biochemical recurrence. This recommendation is due to "increased sensitivity and specificity of PSMA-PET tracers for detecting micrometastatic disease compared to conventional imaging". Conventional imaging is also noted as useful for workup of recurrence or progression. For individuals

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treated with radiation therapy, NCCN stated that suspected recurrence can also be imaged using these modalities. In the setting of distant metastatic disease, CT imaging along with bone scan is the mainstay of imaging with PET/CT reserved for inconclusive conventional imaging or oligo-/low volume disease that needs confirmation. NCCN stated "CT provides a high level of anatomic detail, and may detect gross extracapsular disease, nodal metastatic disease, and/or visceral metastatic disease." PSMA imaging at baseline is medically necessary for individuals being considered for 177Lu-PSMA-617 (Pluvicto®) treatment.[1]

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Prostate Cancer – Follow-up On Active Surveillance (ONC-19.4)

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Active surveillance is being increasingly utilized in prostate cancer, and this therapeutic option involves regimented monitoring of an individual with known diagnosis of low-risk prostate cancer for disease progression, without specific anticancer treatment. While being treated with active surveillance, an individual is generally considered a potential candidate for curative intent treatment approaches in the event that disease progression occurs.

It is important to distinguish active surveillance from watchful waiting (or observation), which is generally employed in individuals with limited life expectancy. Watchful waiting involves cessation of routine monitoring and treatment is initiated only if symptoms develop.

Current active surveillance guidelines suggest the following protocol:

- PSA every 6 months
- Digital Rectal Exam (DRE) every 12 months
- Repeat prostate biopsy every 12 months
- Repeat mpMRI (CPT® 72195 or CPT® 72197) no more often than every 12 months

Indication	Medically Necessary Imaging Study
Routine monitoring on active surveillance protocol	• MRI Pelvis without (CPT® 72195) or without and with contrast (CPT® 72197) at initiation of active surveillance, and every 12 months thereafter
Planning for re-biopsy to be done by MRI/US fusion technique	• 3D Rendering (CPT® 76376 or CPT® 76377)

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Indication	Medically Necessary Imaging Study
For ANY of the following: • Progression is suspected based on DRE changes or rising PSA and a recent TRUS biopsy was negative • Repeat TRUS biopsy shows progression to a higher Gleason score	• MRI Pelvis without (CPT® 72195) or MRI Pelvis without and with contrast (CPT® 72197)
Individuals on active surveillance who are noted to have progression and have plans to initiate treatment	• Imaging studies for initial staging as per **ONC-19.2**

Evidence Discussion

For certain individuals who fall into a low-risk category, close monitoring in the absence of treatment can be pursued with the intent to offer curative therapy in the event progression occurs. Current guidelines include PSA every 6 months, DRE every 12 months, repeat prostate biopsy every 12 months and repeat mpMRI no more often than every 12 months. NCCN stated that a metastatic staging evaluation is not medically necessary for those on active surveillance. With progression and the decision to pursue treatment, imaging is performed according to the same principles as stated in initial staging.[1]

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Surveillance/Follow-up For Treated Prostate Cancer (ONC-19.5)

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Indication	Medically Necessary Imaging Study
ANY of the following: • Asymptomatic or stable chronic symptoms • Stable DRE findings • Stable PSA levels	• Advanced imaging is not routinely medically necessary for surveillance

Evidence Discussion

For individuals who are asymptomatic or have chronic stable findings to include DRE and PSA, advanced imaging is not routinely indicated. This form of monitoring is also referred to as observation. NCCN stated that the advantages of observation avoidance of "possible side effects of unnecessary confirmatory testing and definitive therapy".[1]

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Testicular, Ovarian and Extragonadal Germ Cell Tumors (ONC-20)

Guideline

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Testicular, Ovarian and Extragonadal Germ Cell Tumors – Initial Work-Up/Staging (ONC-20.1)
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Testicular, Ovarian and Extragonadal Germ Cell Tumors – General Considerations (ONC-20.0)

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- This section applies to primary germ cell tumors occurring outside the central nervous system for individual's aged >15 years at the time of initial diagnosis. Individuals aged ≤15 years at diagnosis should be imaged according to pediatric guidelines in: **Pediatric Germ Cell Tumors (PEDONC-10)** in the Pediatric and Special Populations Oncology Imaging Guidelines.
- These guidelines are for germ cell tumors of the testicle, ovary and extragonadal sites as well as malignant sex cord stromal tumors (granulosa cell and Sertoli-Leydig cell tumors).
- Requests for imaging must state the histologic type of the cancer being evaluated.
- Classified as pure seminomas (dysgerminomas, 40%) or non-seminomatous germ cell tumors (NSGCT, 60%):
  - Pure seminomas are defined as pure seminoma histology with a normal serum concentration of alpha fetoprotein (AFP). Seminomas with elevated AFP are by definition mixed.
  - Required for TNM staging are the tumor marker levels indicated by "S" (TNMS)
  - Mixed tumors are treated as NSGCTs, as they tend to be more aggressive.
  - The NSGCT histologies include:
    - yolk-sac tumors
    - immature (malignant) teratomas
    - choriocarcinomas (<1%)
    - embryonal cell carcinomas (15% - 20%)
    - endodermal sinus tumors (ovarian)
    - combinations of all of the above (mixed)
- MRI in place of CT scans to reduce risk of secondary malignancy is not supported by the peer-reviewed literature. CT scans are medically necessary for surveillance and are the preferred modality of imaging to assess for recurrence.
- PET/CT is considered not medically necessary for evaluation of non-seminomatous germ cell tumors.
- Active surveillance in testicular cancer refers to treatment with surgery (orchiectomy) alone without any additional post-operative treatment such as chemotherapy or radiotherapy.

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Testicular, Ovarian and Extragonadal Germ Cell Tumors – Initial Work-Up/ Staging (ONC-20.1)

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Indication	Medically Necessary Imaging Study
Suspicious testicular mass on ultrasound	EITHER of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) or • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)
After orchiectomy or oophorectomy: • Orchiectomy/oophorectomy is both diagnostic and therapeutic, and imaging was not performed prior to surgery	EITHER of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) or • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)
Prior to initiation of chemotherapy to confirm staging, if prior imaging was performed ≥4 weeks ago	Repeat abdominal imaging with ONE of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) or • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)
For ANY of the following: • Non-seminoma histology • Ovarian germ cell tumor • Abdominal lymphadenopathy noted on CT scan • Abnormal chest x-ray or signs/ symptoms suggestive of chest involvement	• CT Chest with contrast (CPT® 71260)

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Indication	Medically Necessary Imaging Study
Extragonadal Germ Cell Tumor	• CT Chest with contrast (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177)
Pelvic mass suspicious for ovarian etiology	See: **Ovarian Cancer - Suspected/Diagnosis (ONC-21.2)**

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Testicular, Ovarian and Extragonadal Germ Cell Tumors – Restaging/ Recurrence (ONC-20.2)

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Indication	Medically Necessary Imaging Study
Treatment response for individuals with metastatic disease, every 2 cycles	• CT Abdomen and Pelvis with contrast (CPT® 74177) OR • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197) AND • CT with contrast of previously involved body areas
Seminoma with residual mass >3 cm after completion of chemotherapy	• PET/CT (CPT® 78815)
Nonseminoma or pure seminoma with partial response or with residual mass and ALL of the following: • Abnormal AFP or beta-hCG levels • Need to evaluate for occult brain metastases	• MRI Brain without and with contrast (CPT® 70553)
Stage IIA pure seminoma or stage IIA nonseminoma with borderline retroperitoneal lymph nodes on preoperative imaging, 4-8 weeks after preoperative imaging	ONE of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) or • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)
End of therapy evaluation for NSGCT post chemotherapy or post retroperitoneal lymph node dissection (RPLND)	• CT Abdomen and Pelvis with contrast (CPT® 74177)

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Indication	Medically Necessary Imaging Study
Recurrence suspected, including increased tumor markers	• CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast • Ultrasound (CPT® 76856 or CPT® 76857) of the remaining gonad if applicable
Unexplained pulmonary symptoms despite a negative chest x-ray, or new findings on chest x-ray	• CT Chest with contrast (CPT® 71260)
All others	• See: **Surveillance (ONC-20.3)**

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Testicular, Ovarian and Extragonadal Germ Cell Tumors – Surveillance (ONC-20.3)

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Indication	Medically Necessary Imaging Study
Stage I seminoma treated with orchiectomy alone (no radiotherapy or chemotherapy, also called active surveillance)	ONE of the following, every 4 months in year 1, then every 6 months for years 2 and 3, and then annually until year 5: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen with contrast (CPT® 74160) • MRI Abdomen without and with contrast (CPT® 74183) • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)
Stage I seminoma treated with radiotherapy and/or chemotherapy	ONE of the following, annually for 3 years: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen with contrast (CPT® 74160) • MRI Abdomen without and with contrast (CPT® 74183) • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)

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Indication	Medically Necessary Imaging Study
Stage IIA and non-bulky stage IIB seminomas treated with radiotherapy or chemotherapy	ONE of the following, once at 3 months, then once at 9-12 months after completion of therapy, then annually for 2 additional years: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen with contrast (CPT® 74160) • MRI Abdomen without and with contrast (CPT® 74183) • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)
Stage II seminoma treated with primary RPLND and NOT treated with adjuvant chemotherapy	ONE of the following, every 4 months in year 1, every 6 months in year 2, and annually in year 3: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen with contrast (CPT® 74160) • MRI Abdomen without and with contrast (CPT® 74183) • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)
Stage II seminoma treated with primary RPLND AND adjuvant chemotherapy	ONE of the following, at 6 months, 12 months, and 24 months: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen with contrast (CPT® 74160) • MRI Abdomen without and with contrast (CPT® 74183) • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)

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Indication	Medically Necessary Imaging Study
Bulky stage IIB, IIC, and III seminomas treated with chemotherapy	For individuals with ≤3 cm residual mass, ONE of the following every 4 months for 1 year, every 6 months for 1 year, and then annually for 2 additional years: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen with contrast (CPT® 74160) • MRI Abdomen without and with contrast (CPT® 74183) • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197) For individuals with >3 cm residual mass and negative PET scan, ONE of the following at 6 and 12 months after completion of therapy, then annually until year 5: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen with contrast (CPT® 74160) • MRI Abdomen without and with contrast (CPT® 74183) • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197) For individuals with thoracic disease: • CT Chest with contrast (CPT® 71260) every 2 months for 1 year, then every 3 months for 1 year, then annually until year 5 after completion of therapy

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Indication	Medically Necessary Imaging Study
Stage IA non-seminomatous germ cell tumors treated with orchiectomy alone (without risk factors)	ONE of the following, every 4 months for one year, every 6 months in the second year, and then annually for years 3, 4, and 5: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen with contrast (CPT® 74160) • MRI Abdomen without and with contrast (CPT® 74183) • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)
Stage IB non-seminomatous germ cell tumors treated with orchiectomy alone (with risk factors – lymphovascular invasion or invasion into spermatic cord/scrotum)	ONE of the following, every 4 months for years 1 and 2, then every 6 months for year 3, and then once in year 4: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen with contrast (CPT® 74160) • MRI Abdomen without and with contrast (CPT® 74183) • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)
Stage IA/IB non-seminomatous germ cell tumors treated with chemotherapy and/or primary RPLND	ONE of the following, annually for 2 years: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen with contrast (CPT® 74160) • MRI Abdomen without and with contrast (CPT® 74183) • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)

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Indication	Medically Necessary Imaging Study
Stage II-III non-seminomatous germ cell tumors with complete response to chemotherapy +/- post-chemotherapy RPLND	ONE of the following, every 4 months in year 1, every 6 months in year 2, and then annually in year 3: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen with contrast (CPT® 74160) • MRI Abdomen without and with contrast (CPT® 74183) • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197) For individuals with known thoracic disease or thoracic symptoms, every 4 months in year 1, every 6 months in year 2, then annually until year 4 after completion of therapy: • CT Chest with contrast (CPT® 71260)
Stage IIA, IIB, or IIC non-seminomatous germ cell tumors treated with post-primary RPLND AND adjuvant chemotherapy	ONE of the following, once at 3-4 months after completion of RPLND: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen with contrast (CPT® 74160) • MRI Abdomen without and with contrast (CPT® 74183) • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)
Stage IIA or IIB non-seminomatous germ cell tumors treated with post-primary RPLND WITHOUT adjuvant chemotherapy	ONE of the following, once at 4 months after completion of therapy and once in year 2: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen with contrast (CPT® 74160) • MRI Abdomen without and with contrast (CPT® 74183) • MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)

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Indication	Medically Necessary Imaging Study
All stages of ovarian dysgerminoma germ cell tumors	• CT Abdomen and Pelvis with contrast (CPT® 74177) every 4 months for 1 year, every 6 months for 1 year and then annually for 3 years after completion of therapy
All ovarian non-dysgerminoma germ cell tumors • Embryonal tumor • Endodermal sinus tumor • Immature teratoma • Non-gestational choriocarcinoma • Yolk sac • Mixed germ cell tumor	• CT Abdomen and Pelvis with contrast (CPT® 74177) every 4 months for 1 year, every 6 months for 1 year and then annually for 3 years after completion of therapy • CT Chest with contrast (CPT® 71260) every 4 months for 1 year and every 6 months for 1 year after completion of therapy
• Sex cord stromal tumors (male and female) • Mature teratoma	• No routine advanced imaging indicated
Extragonadal germ cell tumors	• CT of the involved region every 3 months for one year and every 6 months for one year.

Evidence Discussion - ONC-20

Initial Evaluation

- American Urological Association guideline recommended scrotal ultrasound with Doppler should be obtained in individuals with a unilateral or bilateral scrotal mass suspicious for neoplasm and that MRI should not be used in the initial evaluation and diagnosis of a testicular lesion suspected of being a neoplasm.[12]
- Ultrasound requires no ionizing radiation and is readily available. Overall, ultrasound is relatively quick and non-invasive modality to evaluate a testicular lesion. There are relatively few disadvantages of ultrasound for testicular lesions and primarily relate to sonographer experience.
- As advanced imaging modalities, CT and MRI offer excellent 3-D resolution. A CT scan can require a significant dose of ionizing radiation, but the speed of image acquisition reduces the potential for motion artifact. MRI yields better soft contrast resolution than CT and does not expose individuals to ionizing radiation, but due to longer image time is motion artifact-prone and may require sedation.

Seminoma:

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- NCCN recommended CT of the abdomen and pelvis with contrast or MRI of the abdomen and pelvis with and without contrast, and a chest x-ray. Chest CT with contrast is recommended if there is a positive finding on abdomen CT or abnormal chest x-ray.[1]

Nonseminoma:

- NCCN recommended CT of the abdomen, pelvis and chest with contrast or MRI of the abdomen and pelvis with and without contrast in addition to a chest CT with contrast.[1]

Surveillance

Pure seminoma:[1,13-16]

- Chest radiography is sufficient when compared with CT for follow-up of stage 1 pure seminoma and is recommended by NCCN. While CT is more sensitive than radiography for detecting recurrent disease in the chest, this added sensitivity is offset by lower specificity and a higher false positive detection rate for abnormalities that are not metastatic.
- Scrotal US does not have a role in the restaging of men with testicular cancer that has been established by orchiectomy, unless there is concern for contralateral tumor or equivocal clinical exam.
- CT Abdomen and Pelvis is the reference standard imaging test used for assessing the retroperitoneum. It is rapid, reproducible, and provides excellent imaging of the para-aortic and paracaval regions but does expose individuals to significant ionizing radiation.
- MRI of the abdomen and pelvis
  - MRI has comparable accuracy with CT for the detection of metastatic retroperitoneal lymph nodes and has the benefit of no ionizing radiation. The disadvantage of MRI is longer imaging time which can lead to motion artifact.
- CT of the abdomen and pelvis is the standard imaging test used for assessing the retroperitoneum for nodal metastasis but does expose the individual to high levels of ionizing radiation.
- NCCN guidelines recommended chest radiography for the surveillance of stage I nonseminomatous testicular cancer but chest CT with contrast is preferred in the presence of thoracic symptoms.

Nonseminoma:[1]

- CT of the abdomen and pelvis is the standard imaging test used for assessing the retroperitoneum for nodal metastasis but does expose the individual to high levels of ionizing radiation.

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- NCCN guidelines recommended chest radiography for the surveillance of stage 1 nonseminomatous testicular cancer but chest CT with contrast is preferred in the presence of thoracic symptoms.
- MRI of the abdomen and pelvis shows comparable accuracy with CT in the detection of metastatic retroperitoneal lymph nodes and does not have high levels of ionizing radiation but is subject to motion artifact due to longer imaging time.
- Scrotal US does not have a role in the restaging of men with testicular cancer that has been established by orchiectomy, unless there is concern for contralateral tumor or equivocal clinical exam.

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References (ONC-20)

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2. Armstrong DK, Alvarez RD, Backes FJ, et. al. National Comprehensive Cancer Network (NCCN) Guidelines Version 3.2025 – July 16, 2025. Ovarian cancer, including fallopian tube cancer and primary peritoneal cancer, available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Ovarian cancer V3.2025 – July 16, 2025. ©2025 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines ™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines™, go online to NCCN.org.
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Ovarian Cancer (ONC-21)

Guideline

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Ovarian Cancer – General Considerations (ONC-21.0)

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- Ovarian cancers include: epithelial ovarian cancers, ovarian cancers of low malignant potential and mixed Müllerian tumors, primary peritoneal and fallopian tube cancers.
  - There are five main types of epithelial ovarian cancers:
    - High-grade serous carcinoma (HGSC) (70%)
    - Endometrioid carcinoma (EC) (10%)
    - Clear cell carcinoma (CCC) (10%)
    - Mucinous carcinoma (MC) (3%)
    - Low-grade serous carcinoma (LGSC) (<5%)
- Borderline tumors (formerly referred to as tumors of low malignant potential) usually have some feature of carcinoma when they recur.
- Fallopian tube and primary peritoneal are usually serous carcinoma.
- Germ cell tumors and sex cord stromal tumors (granulosa cell tumors), are imaged according to **Testicular, Ovarian and Extragonadal Germ Cell Cancer (ONC-20)**.

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Screening for Ovarian Cancer (ONC-21.1)

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Indication	Medically Necessary Study
High-Risk Factors: • Family history of BRCA 1 or BRCA 2 mutations • Family history of ovarian cancer • Hereditary ovarian cancer syndrome that includes ovarian, breast, and/or endometrial and gastrointestinal cancers [Lynch II syndrome] in multiple members of two to four generations • Low parity • Decreased fertility • Delayed childbearing	• The use of advanced imaging for ovarian cancer screening is considered not medically necessary. • Genetic counseling is recommended for women with an increased-risk family history.
Known BRCA 1 or BRCA 2 mutation	• Transvaginal ultrasound (CPT® 76830), combined with CA-125 for ovarian cancer screening is medically necessary annually starting at age 30, until risk-reducing salpingo-oophorectomy is performed.

Evidence Discussion

According to ACR Appropriateness Criteria for ovarian cancer screening, any imaging in an average-risk individual is "usually not appropriate."[5]

There is much debate about the role of imaging in screening for ovarian cancer. This cancer has a low prevalence but is the leading cause of mortality in women in the United States. Average lifetime risk is 1.3%. There are factors that increase the risk such as family history, BRCA 1 or BRCA 2 mutations, nulliparity, lack of hormonal contraceptive use, and lack of breastfeeding. Genetic predisposition is associated with the highest increase in risk.

In individuals who are considered high-risk (personal or family history, genetic predisposition or elevated CA-125) ultrasound and color Doppler may be appropriate annual screening along with CA-125. Lu, et al. demonstrated a PPV 40% with specificity

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of 99.9% using ROCA.[11] Studies showed that the risk for developing ovarian cancer increases with age beginning around age 30 years.[12]

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Ovarian Cancer – Suspected/Diagnosis (ONC-21.2)

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- See: **Complex Adnexal Masses (PV-5.3)** for imaging guidelines for evaluation of suspected ovarian malignancies.
- To differentiate the origin of pelvic masses that are not clearly of ovarian origin, see: **Suspected Adnexal Mass (PV-5.1)**.

Indication	Medically Necessary Imaging
• Pelvic signs or symptoms • Palpable pelvic mass	• Transvaginal (TV) ultrasound imaging (CPT® 76830) and/or Pelvic ultrasound (CPT® 76856 or CPT® 76857)
• Ultrasound shows complex and/or solid adnexal mass suspicious for ovarian malignancy or • Any suspicious signs/symptoms for ovarian malignancy (ascites, abdominal symptoms such as distension or tenderness, elevated CA-125, elevated LFTs, obstructive uropathy*)	ANY of the following: • MRI Pelvis without and with contrast (CPT® 72197) ◦ MRI Pelvis without contrast (CPT® 72195) if contrast is contraindicated • CT Abdomen and Pelvis with contrast (CPT® 74177) ◦ MRI Abdomen and MRI Pelvis without and with contrast (CPT® 74183 and CPT® 72197) are medically necessary in lieu of CT for individuals with renal insufficiency or contrast allergy. ◦ CT Abdomen and Pelvis without and with contrast (CT Urogram – CPT® 74178) only for symptoms of obstructive uropathy*

Evidence Discussion

If there is a question about the pelvic mass evaluation by ultrasound, transvaginal or pelvic ultrasound using O-RADS or IOTA is medically necessary to clarify risk before surgery. Accurate diagnosis of adnexal pathology is imperative in order to limit invasive interventions for benign lesions and improve preoperative triage to a gynecologic oncologist for high-risk lesions.[16] In order to standardize reporting of adnexal lesions, the American College of Radiology (ACR) has created the Ovarian-Adnexal Reporting and Data-System (O-RADS). A meta-analysis of 26 studies demonstrated that O-RADS

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has high sensitivity for detection of malignancy (95%).[16] A classification of O-RADS US Category 2 has an extremely low risk of malignancy (<1%), while a Category 5 has a high risk of malignancy (≥50%). For an indeterminate lesion on ultrasound or features concerning for malignancy, adjunct imaging with MRI is supported to aid in preoperative triage. For individuals who have renal insufficiency and therefore are unable to undergo contrasted CT imaging of the abdomen and pelvis, the accepted substitute imaging is MRI with contrast.[1] This imaging will provide the necessary level of soft tissue detail that would not be achievable with a non-contrasted CT.

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Ovarian Cancer – Initial Work-Up/Staging (ONC-21.3)

ON.OC.0021.3.A
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Indication	Medically Necessary Imaging Study
Initial staging of all newly diagnosed ovarian cancer, if imaging has not yet been performed	• CT Abdomen and Pelvis with contrast (CPT® 74177) ◦ MRI Abdomen and MRI Pelvis without and with contrast (CPT® 74183 and CPT® 72197) in lieu of CT for individuals with renal insufficiency or contrast allergy • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) for: ◦ Abnormal signs/symptoms of pulmonary disease ◦ Abnormal chest x-ray ◦ Concern for metastatic disease (i.e., elevated tumor markers, abdominal symptoms)
ANY of the following: • Primary peritoneal disease with biopsy-proven malignancy consistent with ovarian carcinoma • Elevated tumor markers with negative or inconclusive CT imaging	ONE of the following: • MRI Abdomen without and with contrast (CPT® 74183) and/or MRI Pelvis without and with contrast (CPT® 72197) OR • PET/CT (CPT® 78815)
If both CT and MRI are inconclusive	• PET/CT (CPT® 78815)
If CT, MRI, and PET/CT are inconclusive	• PET/MRI (CPT® 78813 and 76498)

Evidence Discussion

If advanced imaging was not already performed, it is necessary to image the abdomen and pelvis with CT. NCCN stated that advanced imaging may improve assessment of metastases, staging, and preoperative planning.[1] For individuals who have renal

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insufficiency and therefore are unable to undergo contrasted CT imaging of the abdomen and pelvis, the preferred substitute imaging is MRI with contrast. This imaging will provide the necessary level of soft tissue detail that would not be achievable with a non-contrasted CT. For those with primary peritoneal disease or inconclusive or conflicting CT imaging, NCCN stated "MRI has been shown to provide equivalent accuracy for staging and comparable accuracy for predicting peritoneal tumor volume, and can be useful if CT results are inconclusive".[1] Chest imaging via CT either with or without contrast is necessary for suspected pulmonary disease or if there is concern for metastatic disease. NCCN stated this imaging is helpful to detect pleural or pulmonary metastases, as well as pleural effusion, which may help with treatment planning.[1] PET is a helpful tool in evaluation of indeterminate lesions on other imaging as it is shown to have high accuracy for detection of metastases.[1]

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Ovarian Cancer – Restaging/Recurrence (ONC-21.4)

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Indication	Medically Necessary Imaging Study
Completely resected or definitively treated with chemotherapy and normal(ized) tumor markers	• No advanced imaging
ANY of the following: • Unresected disease • Unknown preoperative markers • Difficult or abnormal examination • Elevated LFTs • Elevated tumor markers (CA-125, inhibin) • Signs or symptoms of recurrence	• CT Abdomen and Pelvis with contrast (CPT® 74177) ◦ MRI Abdomen and MRI Pelvis without and with contrast (CPT® 74183 and CPT® 72197) in lieu of CT for individuals with renal insufficiency or contrast allergy. • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) for ANY of the following: ◦ Known prior thoracic disease ◦ New or worsening pulmonary symptoms ◦ New or worsening chest x-ray findings ◦ Rising tumor markers (CA-125, inhibin)
Monitoring response to treatment (every 2 cycles, or ~every 6 to 8 weeks)	• CT Abdomen and Pelvis with contrast (CPT® 74177) ◦ MRI Abdomen and MRI Pelvis without and with contrast (CPT® 74183 and CPT® 72197) in lieu of CT for individuals with renal insufficiency or contrast allergy. • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) for ANY of the following: ◦ Known prior thoracic disease ◦ New or worsening pulmonary symptoms ◦ New or worsening chest x-ray findings

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Indication	Medically Necessary Imaging Study
• CT negative or inconclusive and CA-125 continues to rise or elevated LFTs • Conventional imaging failed to demonstrate tumor or if persistent radiographic mass with rising tumor markers	ONE of the following: • MRI Abdomen and MRI Pelvis without and with contrast (CPT® 74183 and CPT® 72197) OR • PET/CT (CPT® 78815)
If both CT and MRI are inconclusive	• PET/CT (CPT® 78815)
If CT, MRI, and PET/CT are inconclusive	• PET/MRI (CPT® 78813 and 76498)

Evidence Discussion

If disease was completely resected and normal CA-125 or other markers normal, then no imaging is needed. If there any question or signs or symptoms of recurrence then the appropriate imaging is similar to that of initial staging. To monitor response to treatment, CT is appropriate every two cycles.

NCCN stated that advanced imaging may improve assessment of metastases and assist in staging.[1] For individuals who have renal insufficiency and therefore are unable to undergo contrasted CT imaging of the abdomen and pelvis, the preferred substitute imaging is MRI with contrast. This imaging will provide the necessary level of soft tissue detail that would not be achievable with a non-contrasted CT. NCCN stated "MRI has been shown to provide equivalent accuracy for staging and comparable accuracy for predicting peritoneal tumor volume, and can be useful if CT results are inconclusive".[1] Thus, MRI is a tool presented for use in the event that CT results are inconclusive or conflict with the clinical picture. Chest imaging via CT either with or without contrast is necessary for suspected pulmonary disease or if there is concern for metastatic disease. NCCN stated this imaging is helpful to detect pleural or pulmonary metastases, as well as pleural effusion, which may help with treatment planning.[1] PET/CT is a helpful tool in evaluation of indeterminate lesions on other imaging as it is shown to have high accuracy for detection of metastases.[1]

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Ovarian Cancer – Surveillance (ONC-21.5)

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Indication	Medically Necessary Imaging Study
Stages I-III	• Advanced imaging is not routinely indicated for surveillance
Measurable metastatic disease on maintenance therapy or being monitored off therapy	Every 3 months for up to 5 years after completion of active treatment: • CT Abdomen and Pelvis with contrast (CPT® 74177) ◦ MRI Abdomen and MRI Pelvis without and with contrast (CPT® 74183 and CPT® 72197) in lieu of CT for individuals with renal insufficiency. • CT with contrast of previously involved body areas • CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) for known history of chest involvement

Evidence Discussion

Stages I to III there is no need for advanced imaging if there are no signs or symptoms. If on maintenance or if there is measurable disease present, CT of the areas involved every three months for up to 5 years. For individuals who have renal insufficiency and therefore are unable to undergo contrasted CT imaging of the abdomen and pelvis, the preferred substitute imaging is MRI with contrast. This imaging will provide the necessary level of soft tissue detail that would not be achievable with a non-contrasted CT.[1]

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Uterine Cancer (ONC-22)

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Uterine Cancer – General Considerations (ONC-22.0)

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- Gestational trophoblastic neoplasia (GTN) – see: **Molar Pregnancy and Gestational Trophoblastic Neoplasia (GTN) (PV-16.1)** in the Pelvic Imaging Guidelines.
- Most common cell type is adenocarcinoma. Uterine sarcomas are also imaged according to this guideline.
- Staging of uterine cancer is primarily surgical. Advanced imaging is not routinely medically necessary pre-operatively for laparoscopic/minimally invasive surgery unless initial staging criteria are met. Pelvic and para-aortic lymphadenectomy can still be performed.

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Uterine Cancer – Suspected/Diagnosis (ONC-22.1)

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- See: **Abnormal Uterine Bleeding (PV-2.1)** in the Pelvic Imaging Guidelines for evaluation of suspected uterine malignancies.

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Uterine Cancer – Initial Work-Up/Staging (ONC-22.2)

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Indication	Medically Necessary Imaging Study
ANY of the following: • Extra-uterine disease suspected • To assess local extent of tumor prior to fertility-sparing surgery for well-differentiated Stage IA (grade 1) uterine cancer • Poor surgical candidate (due to medical comorbidities) considering medical therapy	• MRI Pelvis without and with contrast (CPT® 72197) • Transvaginal ultrasound (CPT® 76830) if MRI is contraindicated • Chest x-ray ◦ CT Chest with contrast (CPT® 71260) for: ▪ New or worsening pulmonary symptoms ▪ New or worsening chest x-ray findings In addition, for surgical staging: • Lymph system imaging (lymphoscintigraphy, CPT® 78195) ◦ SPECT/CT (CPT® 78830) if requested
ANY of the following: • Abdominal symptoms or abnormal examination findings • Elevated LFTs • Other imaging studies suggest liver involvement	ONE of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen with contrast (CPT® 74160)

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Indication	Medically Necessary Imaging Study
ANY of the following high-risk histologies: • Papillary serous • Clear cell • High-grade/poorly differentiated endometrioid carcinoma • Uterine sarcomas: ◦ Carcinosarcoma ◦ Soft tissue sarcoma of the uterus ◦ Leiomyosarcoma ◦ Rhabdomyosarcoma ◦ Undifferentiated sarcoma ◦ Endometrial stromal sarcoma	• CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast • Lymph system imaging (lymphoscintigraphy, CPT® 78195) ◦ SPECT/CT (CPT® 78830) if requested
Tumors detected incidentally or incompletely staged surgically ***and*** ANY of the following high-risk features: • Myoinvasion >50% • Cervical stromal involvement • Lymphovascular invasion • Tumor >2 cm	• CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast
Inconclusive findings on conventional imaging	• PET/CT scan (CPT® 78815)

Evidence Discussion

- The National Comprehensive Cancer Network guidelines (NCCN) for non-fertility sparing treatment recommended considering chest imaging with chest x-ray.[1] If an abnormality is seen on chest x-ray, or if there are symptoms of chest involvement, then chest CT may be performed. Both NCCN and the American College of Radiology noted that MRI of the pelvis is the preferred imaging modality when pretreatment assessment of local tumor extent is indicated due to suspected extra-uterine disease or prior to fertility sparing treatment.[1,6]
- Transvaginal ultrasound can be done if MRI is contraindicated or unavailable.[1]
- If distant metastatic disease is suspected based on abnormal physical examination findings, or for high-grade endometrioid carcinoma, serous, clear cell or

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carcinosarcoma, cross-sectional imaging with CT Chest and CT Abdomen and Pelvis can be considered.[1]

- For incidental findings of endometrial cancer after hysterectomy or incompletely surgically staged with uterine risk factors (myoinvasion of over 50%, cervical stromal involvement or tumor larger than 2 cm), consideration should be given to CT Chest/ Abdomen and Pelvis to evaluate for distant metastatic disease per NCCN guidelines.[1]
- FDG-PET/CT in select individuals if metastases is suspected and other cross-sectional imaging is inconclusive.[1]
- Although endometrial cancer (EC) is surgically staged, preoperative imaging can help tailor surgery and medical treatment in cases as outlined by NCCN and ACR.[1,6] MRI or transvaginal ultrasound is valuable to assess local tumor extent. CT and/or PET-CT is valuable to assess lymph node metastases and distant spread. Preoperative imaging may identify deep myometrial invasion, cervical stromal involvement and metastatic disease. Although these imaging methods may provide information about likely tumor stage, the reported accuracies for preoperative staging of endometrial cancer by conventional imaging have not yet been good enough to replace surgical staging.[8]
- MRI Pelvis has long been established as a valuable imaging method in the preoperative staging of endometrial cancer because it allows the most accurate evaluation of the extent of the pelvis tumor. A meta-analysis showed that the efficacy of contrast-enhanced MRI is significantly better than that of non-contrast MRI and US, and tended toward better results than CT, in evaluating the depth of myometrial invasion in individuals with EC.[6]
- Transvaginal ultrasound may be used if MRI is contraindicated. A study found this imaging modality to have a 79.5% sensitivity and an 89.6% specificity for detecting deep myometrial invasion. However, MRI showed greater accuracy than ultrasound and ultrasound is limited in the setting of concomitant benign disease.[6]
- CT Chest, Abdomen and Pelvis may be used for detection of lymph node metastases, if distant metastatic disease is suspected as per NCCN and ACR listed above.[1,6]
- FDG-PET/CT may be indicated if distant metastatic disease is suspected and CT scans are inconclusive. A meta-analysis reported that the overall pooled sensitivity, specificity, and accuracy of using FDG-PET/CT for detection of lymph node metastasis in EC was 72.0%, 94.0%, and 88.0%, respectively.[6]

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Uterine Cancer – Restaging/Recurrence (ONC-22.3)

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Indication	Medically Necessary Imaging Study
• Unresected disease • Medically inoperable disease • Incomplete surgical staging • Difficult or abnormal examination • Elevated LFTs or rising tumor markers • Signs or symptoms of recurrence	• CT Chest (CPT® 71260) **and** • CT Abdomen and Pelvis with contrast (CPT® 74177)
Monitoring response to chemotherapy (every 2 cycles, ~every 6-8 weeks) for: • Unresected primary disease • Metastatic disease	• CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Chest with contrast (CPT® 71260) for: ◦ Known prior thoracic disease ◦ New or worsening pulmonary symptoms ◦ New or worsening chest x-ray findings
ANY of the following: • After fertility sparing treatment • Inconclusive CT scan findings	• MRI Pelvis without and with contrast (CPT® 72197)
• Inconclusive findings on conventional imaging	• PET/CT (CPT® 78815)

Evidence Discussion

- Recurrence rates for low- or intermediate-risk individuals with endometrial cancer are infrequent. A recent review of post-treatment surveillance and diagnosis of recurrence in women with gynecologic cancers sponsored by the Society of Gynecologic Oncology recommends that radiologic evaluation be used only to investigate suspicion of recurrent disease because of symptoms or physical exam and not for routine surveillance after treatment.[5]
- CT Chest, Abdomen, and Pelvis is useful for suspected recurrence of disease based on abnormal physical examination findings and/or new pelvis, abdominal or pulmonary symptoms.[1] A study reported that 45 asymptomatic individuals had

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routine CT scans, and recurrence was diagnosed by CT in only 2 (4.4%), whereas 37 symptomatic women had CT scans for suspicion of recurrence, and it was confirmed by CT in 17 (46%).[6]

- MRI of the pelvis may be done after fertility sparing treatment for persistent endometrial carcinoma.[1] In individuals with persistent endometrial carcinoma after 6 months of failed hormonal therapy, pelvic MRI to exclude myoinvasion and nodal/ovarian metastasis is recommended before continuing fertility-sparing therapy.[1]
- FDG-PET/CT may give further clinically applicable information in cases where conventional imaging is inconclusive. As per the prior meta-analysis, the overall pooled sensitivity, specificity, and accuracy of using FDG-PET/CT for detection of lymph node metastasis in EC was 72.0%, 94.0%, and 88.0%, respectively.[6]

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Uterine Cancer – Surveillance (ONC-22.4)

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Indication	Medically Necessary Imaging Study
Stage I-III of uterine carcinoma	Advanced imaging is not routinely medically necessary
Measurable metastatic disease on maintenance therapy or being monitored off therapy	Every 3 months for up to 5 years after completion of definitive treatment: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of previously involved body areas
All stages of uterine sarcoma: • Soft tissue sarcoma of the uterus • Leiomyosarcoma • Adenosarcoma • Carcinosarcoma • Rhabdomyosarcoma • Undifferentiated sarcoma • Endometrial stromal sarcoma	CT Chest (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177) every 3 months for 2 years, every 6 months for 3 years, and then every 1-2 years until year 10

Evidence Discussion

- Advanced imaging is not routinely indicated for surveillance for non-metastatic, asymptomatic disease in endometrial cancer. A review of post-treatment surveillance and diagnosis of recurrence in individuals with gynecologic cancers sponsored by the Society of Gynecologic Oncology recommended that radiologic evaluation be used only to investigate suspicion of recurrent disease because of symptoms or physical exam and not for routine surveillance after treatment.[5]
- Measurable metastatic disease can be followed with CT Abdomen and Pelvis and CT of previously involved body areas every 3 months for 5 years after treatment.
- All stages of uterine sarcoma, CT Chest, Abdomen and Pelvis every 3 months for 2 years, every 6 months for 3 years and then every 1-2 years until year 10.[1]

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Gestational Trophoblastic Neoplasia (GTN) (ONC-22.5)

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- The most common form of gestational trophoblastic disease (GTD) is hydatidiform mole (HM), a benign form, also known as molar pregnancy.
  - See: **Molar Pregnancy and GTN (PV-16.1)**
- Gestational trophoblastic neoplastic disorders including a malignant form of GTD, and can present as invasive mole, choriocarcinoma, placental site trophoblastic tumor (PSTT), or epithelioid trophoblastic tumor (ETT). GTN cells are malignant and can metastasize to other organs such as lungs, brain, bone and vagina. These tumors have a high likelihood of cure and treatment with methotrexate usually allows for fertility preservation.
- Surveillance is generally with serial monitoring of hCG levels, and advanced imaging is reserved for high-risk histologies where hCG levels may not be a reliable marker.

Indication	Medically Necessary Imaging Study
Initial staging	• CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177)
EITHER of the following: • Pulmonary metastases noted on CT scan • Signs/symptoms of CNS involvement	• MRI Brain without and with contrast (CPT® 70553)
EITHER of the following: • Monitoring response to systemic therapy (every 2 cycles, i.e., 6-8 weeks) • Suspected progression	• CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177)

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Indication	Medically Necessary Imaging Study
Surveillance for any of the following high risk histologies: • Placental site trophoblastic tumor (PSTT) • Epithelioid trophoblastic tumor (ETT)	Annually for 2 years: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177)

Evidence Discussion

- The most common form of GTD is hydatidiform mole (HM), also known as molar pregnancy. HMs are considered a benign, premalignant disease.[7]
- Initial determination of suspected HM is often made based on ultrasound findings in combination with clinical symptoms and hCG levels.[7]
- Gestational trophoblastic neoplastic disorders include a malignant form of GTD, and can present as invasive mole, choriocarcinoma, placental site trophoblastic tumor (PSTT), or epithelioid trophoblastic tumor (ETT). GTN cells are malignant and can metastasize to other organs such as lungs, brain, bone and vagina.
- Initial staging of GTN includes a CT of chest and CT of abdomen and pelvis.
- If pulmonary metastases are noted on CT Chest or for signs or symptoms of central nervous system (CNS) involvement, MRI Brain is medically necesssary to evaluate for metastatic disease. Rates of CNS metastases are low with post-molar GTN, but approximately 20% of individuals with choriocarcinoma have CNS involvement.[7]
- For monitoring response to treatment or for suspected progression CT Chest, Abdomen and Pelvis is performed.
- Post-treatment surveillance in general is done with monitoring of hCG levels in individuals with post-molar GTN or choriocarcinoma, where hCG is a reliable tumor marker.[7]
- Surveillance imaging for placental site or epithelioid trophoblastic tumor can be done with CT Chest, Abdomen, and Pelvis annually for 2 years. Post-treatment imaging is medically necessary for follow-up after treatment of PSTT and ETT, where hCG is a less reliable tumor marker.[7]

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Cervical Cancer – Surveillance (ONC-23.4)
References (ONC-23)

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Cervical Cancer – General Considerations (ONC-23.0)

ON.CV.0023.0.A

v1.0.2026

- Primary histology for cervical cancer is squamous cell. Other, less common histologies are adenosquamous and adenocarcinoma. If biopsy is consistent with one of these less common histologies, it is necessary to clarify that tumor is not of primary uterine origin.
- If the primary histology is uterine in origin, follow imaging recommendations for uterine cancer, see: **Uterine Cancer (ONC-22)**.

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Cervical Cancer – Suspected/Diagnosis (ONC-23.1)

ON.CV.0023.1.A
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Indication	Medically Necessary Imaging Study
All	• Advanced imaging is not medically necessary prior to biopsy

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Cervical Cancer – Initial Work-Up/ Staging (ONC-23.2)

ON.CV.0023.2.A
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Indication	Medically Necessary Imaging Study
All individuals with one of the following: • Stage I-IVA • Stage IVB amenable to local treatment	• MRI Pelvis without and with contrast (CPT® 72197)
Stage IB1-IB3, non-fertility sparing treatment	In addition to MRI Pelvis above, any ONE of the following combinations: • PET/CT (CPT® 78815) or • CT Chest with contrast (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177) or • PET/MRI (CPT® 78813 and CPT® 76498)
ANY of the following: • Stage 1B1-IB3, fertility-sparing treatment • Stage II-IVA • Any size cervical cancer incidentally found in a hysterectomy specimen	In addition to MRI Pelvis above, any ONE of the following combinations: • PET/CT (CPT® 78815) or • CT Chest with contrast (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177) or • CT Chest without contrast (CPT® 71250) and CT Abdomen and Pelvis with contrast (CPT® 74177)

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Indication	Medically Necessary Imaging Study
Small cell neuroendocrine carcinoma of the cervix (NECC)	MRI Brain without and with contrast (CPT® 70553) and any ONE of the following combinations: • PET/CT (CPT® 78815) or • CT Chest with contrast (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177) or • CT Chest without contrast (CPT® 71250) and CT Abdomen and Pelvis with contrast (CPT® 74177)
Inconclusive findings on conventional imaging	• PET/CT (CPT® 78815)

Evidence Discussion

- MRI Pelvis is recommended by NCCN in virtually all individuals, with exception of stage IVB not amenable to local treatment. MRI Pelvis imaging is used to assess local disease extent, to help with surgical treatment planning, and to help with any radiation treatment planning.[1]
- Systemic imaging is indicated to assess for lymphadenopathy and distant metastases. The goal of systemic imaging is to evaluate for metastatic disease. CT imaging of the chest, abdomen, and pelvis are useful; PET/CT is the recommended study of choice in higher stages of disease. NCCN stated of non-fertility-sparing approaches, "depending on their stage and disease bulk, individuals with stage IB or IIA tumors can be treated with surgery, RT, or concurrent chemoradiation. A combined PET/CT scan can be performed to rule out extra pelvic disease before deciding how to treat these individuals. Neck/chest/abdomen/pelvis/groin FDG-PET/CT is preferred to evaluate metastatic disease. A chest/abdomen/pelvis CT or FDG-PET/MRI can also be performed."[1]
- Meta-analyses have shown CT with intravenous (IV) contrast to have 43%-55% sensitivity and 71% specificity for parametrial invasion, and 41% sensitivity and 92% specificity for bladder invasion In comparison, MRI demonstrated 71% specificity (95% confidence interval [CI], 62%-79%) and 91% sensitivity (95% CI, 88%-93%) for parametrial invasion, and 84% sensitivity (95% CI, 57%-95%) and 95% specificity (95% CI, 87%-98%) for bladder invasion.
- Small cell neuroendocrine carcinoma of the cervix (NECC) is considered an aggressive form of cervical cancer. The NCCN-recommended studies are adapted

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from their own guidelines on neuroendocrine tumors and non-small cell lung cancers.[1] Brain imaging is medically necessary in this cell type to evaluate for metastatic disease to the brain.

- PET/CT remains a useful tool for evaluation of inconclusive findings on conventional imaging.

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Cervical Cancer – Restaging/Recurrence (ONC-23.3)

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Indication	Medically Necessary Imaging Study
Stage I treated with definitive surgery	• See: **Cervical Cancer – Surveillance (ONC-23.4)**
EITHER of the following: • Stage IB3 • Stage I treated with post-operative adjuvant radiation or chemoradiation due to positive nodes, positive parametria, positive margins, or local cervical factors	• PET/CT (CPT® 78815) 3-6 months post-completion of therapy
Stage II-IV	ONE of the following within 3-6 months of completion of therapy: • PET/CT (CPT® 78815) or • CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast)
Small cell NECC, treated with primary chemoradiation	ONE of the following after completion of therapy: • PET/CT (CPT® 78815) and MRI Brain without and with contrast (CPT® 70553) or • CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast and MRI Brain without and with contrast (CPT® 70553)
Inconclusive findings on CT scan or PET/CT	MRI Pelvis without and with contrast (CPT® 72197)

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Indication	Medically Necessary Imaging Study
Unresectable disease or metastatic disease on systemic treatment	Every 2 cycles of treatment (commonly every 6 to 8 weeks): • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of other involved or symptomatic areas
Inconclusive conventional imaging	• PET/CT (CPT® 78815)
Suspected or biopsy proven recurrence	EITHER of the following, not both: • PET/CT (CPT® 78815) OR • CT Chest (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177)

Evidence Discussion

- The main purpose of imaging after primary surgery is to determine whether distant metastases are present.[1] Thus, repeating systemic imaging for certain individuals in whom surgery was not definitive treatment is recommended.
- For unresectable or metastatic disease on systemic treatment, CT Chest/Abdomen/Pelvis every 2 cycles is appropriate.
- PET/CT remains a useful tool for evaluation of inconclusive conventional imaging. MRI Pelvis, given its excellent resolution of soft-tissue imaging, is a recommended tool for evaluation of an inconclusive CT or PET/CT.[1]

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Cervical Cancer – Surveillance (ONC-23.4)

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Indication	Medically Necessary Imaging Study
Stage I disease treated with fertility sparing approach	• MRI Pelvis without and with contrast (CPT® 72197) at 6 months after surgery and then annually for 2-3 years
Small cell NECC	Once, 3-6 months after completion of therapy: • PET/CT (CPT® 78815) Then, every 3 months for 1 year, then every 6 months: • CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast and MRI Brain without and with contrast (CPT® 70553)
All other individuals	• No routine advanced imaging in asymptomatic individuals.

Evidence Discussion

With stage I post fertility-sparing treatment, MRI Pelvis is supported by NCCN for surveillance imaging at 6 months post-operatively and then annually for 2-3 years. For small-cell NECC, NCCN supported PET/CT at completion of therapy and supported ongoing surveillance, but a timeframe is not provided. There are little data in the medical literature specific to this topic. It is therefore reasonable to follow the NCCN-recommended surveillance schedule for extrathoracic small-cell neuroendocrine tumors for small-cell NECC. For small-cell NECC, NCCN supported PET/CT at completion of therapy and supported ongoing surveillance, but a timeframe is not provided. There are little data in the medical literature specific to this topic. It is therefore reasonable to follow the NCCN-recommended surveillance schedule for extrathoracic small cell neuroendocrine tumors for small cell NECC.[1]

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Anal Cancer & Cancers of the External Genitalia (ONC-24)

Guideline

Anal Carcinoma – General Considerations (ONC-24.0)
Anal Carcinoma – Suspected/Diagnosis (ONC-24.1)
Anal Carcinoma – Initial Work-up/Staging (ONC-24.2)
Anal Carcinoma – Restaging/Recurrence (ONC-24.3)
Anal Carcinoma – Surveillance (ONC-24.4)
Cancers of External Genitalia – General Considerations (ONC-24.5)
Cancers of External Genitalia – Initial Work-Up/Staging (ONC-24.6)
Cancers of External Genitalia – Restaging/Recurrence (ONC-24.7)
Cancers of External Genitalia – Surveillance (ONC-24.8)
References (ONC-24)

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Anal Carcinoma – General Considerations (ONC-24.0)

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- Most are squamous cell carcinomas, although some transitional and cloacogenic carcinomas are seen.
- Adenocarcinoma of the anal canal is managed as rectal cancer according to **Colorectal and Small Bowel Cancer (ONC-16)**.
- Squamous cell carcinoma of the perianal region (up to 5 cm radius from the anal verge) are imaged according to anal carcinoma guidelines.
- Bowen's disease and Paget's disease of the perianal and perigenital skin are considered non-invasive/in-situ conditions and do not routinely require advanced imaging. See: **Non-Melanoma Skin Cancers – Initial Work-up/Staging (ONC-5.6)**.

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Anal Carcinoma – Suspected/Diagnosis (ONC-24.1)

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Indication	Medically Necessary Imaging Study
All	• No advanced imaging prior to biopsy

Evidence Discussion

Advanced imaging prior to biopsy is not medically necessary as most tumors are staged clinically by direct examination and microscopic confirmation (biopsy).[1]

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Anal Carcinoma – Initial Work-up/ Staging (ONC-24.2)

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Indication	Medically Necessary Imaging Study
All individuals	• CT Chest with contrast (CPT® 71260) and Any ONE of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Abdomen with contrast (CPT® 74160) and MRI Pelvis without and with contrast (CPT® 72197)
• Stage II-III Squamous Cell Carcinoma of the Anal Canal and no evidence of metastatic disease by conventional imaging • Inconclusive findings on conventional imaging	• PET/CT (CPT® 78815)

Evidence Discussion

All individuals undergo CT Chest with contrast and either CT Abdomen and Pelvis with contrast or CT Abdomen with contrast and MRI Pelvis without/with contrast. CT allows information on whether there is other organ involvement or possible disease spread. PET/CT is supported in stage II-III disease with no evidence of distant metastatic disease by conventional imaging or if conventional imaging is inconclusive. PET/CT is useful in assessing pelvic nodes and has been shown to change the nodal status/TNM stage in up to 41% of individuals. PET/CT does not replace a diagnostic CT in initial staging.[1,11]

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Anal Carcinoma – Restaging/Recurrence (ONC-24.3)

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Indication	Medically Necessary Imaging Study
Stage I treated with complete surgical resection	• See: **Anal Carcinoma – Surveillance (ONC-24.4)** for surveillance guidelines
Stages I, II and III – post chemoradiation evaluation	Any ONE of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) • MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast
Metastatic (stage IV) disease	• CT Abdomen and Pelvis with contrast (CPT® 74177) every 2 cycles (generally 6 to 8 weeks) on treatment • CT Chest with contrast (CPT® 71260) if chest x-ray is abnormal or if symptoms of chest involvement
• Difficult or abnormal examination • Elevated LFTs • Signs or symptoms of recurrence • Biopsy proven recurrence	Preferably using same imaging studies as used in initial imaging: • CT Chest (CPT® 71260) with contrast and Any ONE of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) • MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast
Inconclusive findings on conventional imaging	• PET/CT (CPT® 78815)

Evidence Discussion

Due to low risk of recurrence, stage I treated with complete surgical resection would follow surveillance guidelines that do not recommend any routine imaging. For stages I, II, and III treated with chemoradiation, CT Abdomen and Pelvis, or MRI Abdomen and Pelvis should be obtained upon completion of therapy. Stage IV disease on treatment should undergo CT Abdomen and Pelvis every 2 cycles with imaging of the chest if chest x-ray is abnormal or symptoms develop. If recurrence is suspected, CT Chest

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with either CT Abdomen and Pelvis or MRI Abdomen and Pelvis should be performed. NCCN stated that imaging for recurrence is preferred to mirror the same imaging studies as used in initial imaging. PET/CT is indicated for inconclusive findings on conventional imaging.[1]

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Anal Carcinoma – Surveillance (ONC-24.4)

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Indication	Medically Necessary Imaging Study
Stage I	• Advanced imaging is not routinely indicated for surveillance
• Stage II • Stage III • Local recurrence treated definitively	• CT Chest (CPT® 71260) with contrast or CT Chest without contrast (CPT® 71250) annually for 3 years • And ANY one of the following annually for three years: ◦ CT Abdomen and Pelvis with contrast (CPT® 74177) ◦ MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)
Stage IV – measurable metastatic disease on maintenance treatment or being observed off treatment	Every 3 months for up to 5 years after completion of all treatment: • CT Chest (CPT® 71260) with contrast • CT Abdomen and Pelvis with contrast (CPT® 74177)

Evidence Discussion

For individuals with Stage II-III disease or had definitive treatment of a local recurrence, CT Chest with or without contrast plus either CT Abdomen and Pelvis with contrast or MRI Abdomen and Pelvis without/with contrast is medically necessary annually for 3 years. NCCN stated that FDG PET/CT is not indicated for surveillance of local recurrence treated definitively.[1]

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Cancers of External Genitalia – General Considerations (ONC-24.5)

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- These imaging guidelines are applicable for squamous cell carcinomas arising from the vulva, vagina, penis, urethra, and scrotum.

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Cancers of External Genitalia – Initial Work-Up/Staging (ONC-24.6)

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Indication	Medically Necessary Imaging Study
Clinical node negative **vulvar** cancer with ANY of the following: • Lesion >2 cm • Any size with stromal invasion >1 mm	• For planned sentinel lymph node evaluation: Lymph system imaging (lymphoscintigraphy, CPT® 78195) ◦ SPECT/CT (CPT® 78830) if requested
For stage II or higher **vulvar** cancer or suspected metastatic vulvar cancer based on one of the following: • Abnormal physical exam findings • Bulky vulvar tumor (≥4 cm or close to critical structures) • Vaginal, urethral, or anal involvement • Delay in presentation or treatment • Pelvic, abdominal, or pulmonary symptoms	ONE of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) OR • CT Abdomen with contrast (CPT® 74160) and MRI Pelvis without and with contrast (CPT® 72197) • CT Chest with contrast (CPT® 71260) is medically necessary only for: ◦ Signs/symptoms suggestive of chest involvement ◦ Abnormal findings on chest x-ray

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Indication	Medically Necessary Imaging Study
Vaginal carcinoma	ONE of the following combinations: • PET/CT (CPT® 78815) and MRI Pelvis without and with contrast (CPT® 72197) or • CT Abdomen and Pelvis with contrast (CPT® 74177) and CT Chest with contrast (CPT® 71260) or • CT Abdomen with contrast (CPT® 74160) and MRI Pelvis without and with contrast (CPT® 72197) and CT Chest with contrast (71260)
Penile carcinoma with ANY of the following: • Non-palpable inguinal lymph nodes and intermediate or high-risk lesion (T1b or any T2 or greater) • Palpable inguinal lymph nodes • Difficult pelvic node assessment on physical exam	Any ONE of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) • MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast • CT Abdomen with contrast (CPT® 74160) and MRI Pelvis without and with contrast (CPT® 72197) • CT Chest with contrast (CPT® 71260)
• Inconclusive findings on conventional imaging • Pelvic nodes enlarged but biopsy not technically feasible	• PET/CT (CPT® 78815)

Evidence Discussion

Lymphoscintigraphy is appropriate for the workup of vulvar cancer since the disease spreads through skin layer and into the lymph system. FIGO surgical staging is used after superficial removal of the lesion. If it is a large (>2 cm) or stromal invasion (>1 mm) then spread is evaluated with CT. CT imaging plays an important role in stage II or higher disease by helping to delineate the extent of tumor and assisting in treatment planning.[3] CT of the chest is valuable if there are signs or symptoms of chest involvement. In the evaluation of vaginal carcinoma, NCCN stated that PET/CT is the preferred imaging for evaluation of metastatic disease (conventional CT of the

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chest, abdomen, and pelvis remains a recommended option). MRI Pelvis is medically necessary in addition to PET/CT or conventional CT for assessment of local disease extent.[14] For the initial workup of penile cancer, cross-sectional imaging with CT or MRI of the abdomen and pelvis are necessary for pelvic node evaluation in circumstances where there is greater chance of lymph node involvement, palpable lymph nodes, or when it is difficult to physically assess potential lymph node involvement.[2] Evaluation of inguinal lymph nodes "has been identified as the single most important prognostic indicator in determining long-term survival in individuals with invasive penile squamous cell carcinoma".[2] MRI can also provide information on depth of tumor invasion.[2] PET/CT remains a problem-solving tool for inconclusive conventional imaging. PET/CT has higher sensitivity for individuals with node-positive penile cancer than those without, thus it is used as a tool of lymph node assessment when biopsy is not technically feasible.[2]

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Cancers of External Genitalia – Restaging/Recurrence (ONC-24.7)

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Indication	Medically Necessary Imaging Study
• Difficult or abnormal examination • Elevated LFTs • Signs or symptoms of recurrence • Biopsy proven recurrence	• CT Chest with contrast (CPT® 71260) And ANY one of the following: • CT Abdomen and Pelvis with contrast (CPT® 74177) • MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast
EITHER of the following: • individuals receiving systemic treatment for measurable disease • At the end of definitive therapy	Any ONE of the following, every 2 cycles (generally 6 to 8 weeks) during treatment at at the end of planned chemotherapy treatment: • CT Abdomen and Pelvis with contrast (CPT® 74177) or • MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast or • CT Abdomen with contrast (CPT® 74160) and MRI Pelvis (CPT® 72197) AND • CT Chest with contrast (CPT® 71260)
Vaginal primary tumor treated with upfront radiation therapy	• PET/CT (CPT® 78815) at least 12 weeks after completion of radiation therapy ◦ MRI Pelvis without and with contrast (CPT® 72197) is medically necessary if PET/CT not available (can be performed sooner than 12 weeks after completion of therapy) ◦ MRI Pelvis without and with contrast (CPT® 72197) is medically necessary for clarification of PET/CT findings
Vulvar carcinoma following definitive primary therapy with chemoradiation or surgery	3-6 months after primary therapy: • MRI Pelvis without and with contrast (CPT® 72197)

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Indication	Medically Necessary Imaging Study
Inconclusive findings on conventional imaging	• PET/CT (CPT® 78815)

Evidence Discussion

Signs or symptoms of recurrence should be imaged with CT or MRI to evaluate for metastatic disease. Specifically for vaginal cancer, PET/CT is preferred to re-image three to four months after the completion of radiation therapy to determine response to treatment while avoiding false-positive from recent radiation. If PET/CT is inconclusive, NCCN stated that MRI is the preferred imaging for clarification.[14] For vulvar cancer, reassessment with MR imaging is necessary to assess response to treatment and re-evaluate lymph node involvement.[3] PET/CT can be used as a tool for evaluation of inconclusive conventional imaging.

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Cancers of External Genitalia – Surveillance (ONC-24.8)

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Indication	Medically Necessary Imaging Study
• All stages of vulvar and vaginal cancers	• See: **ONC-24.7** for post-treatment imaging 3-6 months after completion of therapy. No additional routine advanced imaging for asymptomatic surveillance.
• Penile Cancer: stage I-IIIA	• CT Abdomen and Pelvis with contrast (CPT® 74177) every 6 months for 2 years, and then every 12 months for 2 years
• Penile cancer: stages IIIB-IV	• CT Chest with contrast (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177) every 3 months for one year, then every 6 months for 3 more years

Evidence Discussion

If no symptoms or findings on recent physical examination then advanced imaging is not medically necessary for all stages of vulvar and vaginal cancer.[3,14] For stage I-IIIA penile cancer, the NCCN supported CT Abdomen and Pelvis for surveillance, with chest imaging via radiograph only on the same schedule as CTs. For stages IIIB-IV penile cancer, chest CT is supported for surveillance with more frequent CT Abdomen and Pelvis than in early stage disease.[2]

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Multiple Myeloma and Plasmacytomas (ONC-25)

Guideline

Multiple Myeloma and Plasmacytomas – General Considerations (ONC-25.0)
Multiple Myeloma and Plasmacytomas –Suspected/Diagnosis (ONC-25.1)
Multiple Myeloma and Plasmacytomas – Initial Work-Up/Staging (ONC-25.2)
Multiple Myeloma and Plasmacytomas – Restaging/Recurrence (ONC-25.3)
Multiple Myeloma and Plasmacytomas – Surveillance (ONC-25.4)
References (ONC-25)

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Multiple Myeloma and Plasmacytomas – General Considerations (ONC-25.0)

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- Multiple myeloma (MM) is a neoplastic disorder characterized by the proliferation of a single clone of plasma cells derived from B cells which grows in the bone marrow and adjacent bone, producing skeletal destruction.
- Multiple myeloma group of disorders can be classified as below, which influence imaging modality of choice.

Condition	Monoclonal protein	Bone marrow plasma cells	CRAB criteria**
Solitary Plasmacytoma (biopsy proven tumor containing plasma cells)	<3 gm/dL	Absent	Absent
Monoclonal Gammopathy of Unknown Significance (MGUS)	<3 gm/dL	<10%	Absent
Smoldering Myeloma (SMM) (stage I MM or asymptomatic MM)	≥3 gm/dL	10% - 60%	Absent
Multiple Myeloma (MM)	≥3 gm/dL	≥10%	Present

**CRAB criteria = hypercalcemia, renal insufficiency, anemia, lytic bony lesions

- Diagnosis and monitoring of response to therapy is primarily with laboratory studies that include urine and serum monoclonal protein levels, serum-free light chain levels, LDH and beta-2 microglobulin. Routine advanced imaging to monitor response to treatment is not medically necessary.
- Rarely, (<5%), an individual may have nonsecretory myeloma, which does not produce measurable M-protein. These individuals require imaging as primary method to monitor disease.
- Other conditions that may present with monoclonal gammopathy include:
  - POEMS syndrome: Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal protein and Skin Changes – may also have sclerotic bone lesions and Castleman's disease. See: **Multiple Myeloma and Plasmacytomas – Initial Work-up/Staging (ONC-25.2)** for imaging recommendations.

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- Waldenström's Macroglobulinemia: IgM monoclonal protein along with bone marrow infiltration of small lymphocytes. See: **Waldenström Macroglobulinemia or Lymphoplasmacytic Lymphoma (ONC-27.10)** for imaging recommendations.
- Systemic Light chain Amyloidosis: light chain monoclonal protein in serum or urine with clonal plasma cells in bone marrow, systemic involvement of the kidneys, liver, heart, gastrointestinal tract or peripheral nerves due to amyloid deposition. See: **Multiple Myeloma and Plasmacytomas – Initial Work-up/Staging (ONC-25.2)** and **Cardiac Amyloidosis (CD-3.8)**for imaging recommendations for systemic light chain amyloidosis.

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Multiple Myeloma and Plasmacytomas – Suspected/Diagnosis (ONC-25.1)

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See: **Initial Work-up/Staging (ONC-25.2)**

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Multiple Myeloma and Plasmacytomas – Initial Work-Up/Staging (ONC-25.2)

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Indication	Medically Necessary Imaging Study
Either of the following: • Confirmed myeloma • Myeloma suspected based on any of the following: ◦ Abnormal skeletal survey or other imaging ◦ Abnormal myeloma labs ◦ Signs/symptoms of multiple myeloma	EITHER of the following: • Whole-body low-dose skeletal CT (CPT® 76497) or • Whole-body FDG PET/CT (CPT® 78816)
Inconclusive findings on whole-body low-dose skeletal CT	• PET/CT (CPT® 78815 or CPT® 78816)
To discern smoldering myeloma from active myeloma and whole-body CT or PET are negative or inconclusive	ONE of the following: • MRI Bone Marrow Blood Supply (CPT® 77084) • Whole-body MRI (CPT® 76498) • CT contrast as requested of a specific area to determine radiotherapy or surgical candidacy, or for suspected extra-osseous plasmacytoma
Initial work-up of suspected or known POEMS syndrome	• CT Chest with contrast (CPT® 71260) and • CT Abdomen and Pelvis with contrast (CPT® 74177) • Whole-body FDG PET/CT (CPT® 78816) for sclerotic bone lesions on other imaging

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Indication	Medically Necessary Imaging Study
Initial work-up of suspected or known systemic light chain amyloidosis	• Whole-body low-dose skeletal CT (CPT® 76497) OR Whole-body FDG PET/CT (CPT® 78816) • Additional imaging, base on suspected organ involvement: ◦ CT Chest with contrast (CPT® 71260) ◦ CT Abdomen and Pelvis with contrast (CPT® 74177) For additional imaging related to cardiac involvement, see: **Cardiac Amyloidosis (CD-3.8)**

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Multiple Myeloma and Plasmacytomas – Restaging/Recurrence (ONC-25.3)

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Indication	Medically Necessary Imaging Study
Extra-osseous plasmacytoma response to initial therapy	Repeat imaging with ONE of the following, whichever modality was used at initial diagnosis: • Whole-body low-dose skeletal CT scan (CPT® 76497) • Whole-body FDG PET/CT (CPT® 78816) • Whole-body MRI (CPT® 76498) • CT of any previously involved area, contrast as requested • MRI of any previously involved area, contrast as requested
Known spine involvement with new neurological signs/symptoms or worsening pain	• MRI Cervical (CPT® 72156), Thoracic (CPT® 72157), Lumbar spine (CPT® 72158) without and with contrast
Treatment response assessment • After completion of primary therapy • Non-secretory multiple myeloma • To determine therapy response with inconclusive labs	Repeat imaging with ONE of the modalities below, whichever was used at initial diagnosis: • Whole-body low-dose skeletal CT scan (CPT® 76497) • Whole-body FDG PET/CT (CPT® 78816)
CAR-T cell therapy	Once before treatment and once 30-60 days after completion of treatment: • PET/CT (CPT® 78815 or CPT® 78816)
ANY of the following: • Suspected progression or relapse/recurrence • Suspected progression of MGUS or SMM to a more malignant form	EITHER of the following: • Whole-body low-dose skeletal CT (CPT® 76497) • Whole-body FDG PET/CT (CPT® 78816)

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Indication	Medically Necessary Imaging Study
ANY of the following: • Negative PET will allow change in management from active treatment to maintenance or surveillance. • Inconclusive findings on conventional imaging • Whole-body low-dose skeletal CT (CPT® 76497) is unfeasible and recurrence or progression is suspected	• PET/CT (CPT® 78815 or CPT® 78816)
To discern smoldering myeloma from active myeloma and whole-body CT or PET are negative or inconclusive	ONE of the following: • MRI Bone Marrow Blood Supply (CPT® 77084) • Whole-body MRI (CPT® 76498) • MRI without contrast, or MRI without and with contrast for any previously involved bony area or symptomatic area (including whole spine for spinal symptoms)
Stem cell transplant recipients	ONE of the following, once before transplant and once within 30-100 days after transplant: Imaging should use same modality as initial diagnosis. • Whole-body low-dose skeletal CT scan (CPT® 76497) • MRI Bone Marrow Blood Supply (CPT® 77084) • Whole-body MRI (CPT® 76498) • PET/CT (CPT® 78815 or CPT® 78816)

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Multiple Myeloma and Plasmacytomas – Surveillance (ONC-25.4)

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Indication	Medically Necessary Imaging Study
• Smoldering myeloma • Multiple myeloma	ANY ONE of the following (using same imaging modality used at diagnosis) annually: • Whole-body low-dose skeletal CT (CPT® 76497) • MRI Bone Marrow Blood Supply (CPT® 77084) • Whole-body MRI (CPT® 76498) • Whole-body FDG PET/CT (CPT® 78816)
Solitary plasmacytomas	Any ONE of the following (using same imaging modality used at diagnosis) annually for 5 years: • Whole-body low-dose skeletal CT (CPT® 76497) • MRI Bone Marrow Blood Supply (CPT® 77084) • Whole-body MRI (CPT® 76498) • Whole-body FDG PET/CT (CPT® 78816)

Evidence Discussion

- Bone disease is the most frequent feature of multiple myeloma (MM), occurring in approximately two-thirds of individuals at diagnosis and in nearly all individuals during their disease.[13] Imaging is a key part of the evaluation of all individuals with suspected MM and plays a very important role in the management of MM.[26] It is necessary for detection of lytic bone lesions, which represent a marker of disease-related end-organ damage and are traditionally used to diagnose MM and to establish the need for immediate therapy.[3]
- The detection of bone and bone marrow lesions is crucial in the investigation of multiple myeloma and often dictates the decision to start treatment. Cross-sectional imaging (i.e., CT, PET/CT, MRI) is preferred because these modalities are more sensitive than plain radiographs for the detection of most skeletal lesions in MM.
- Whole-body low-dose CT (WBLDCT) can be used as a baseline assessment of bone involvement. CT is quick, convenient, relatively sensitive, and cost-effective in this scenario. WBLDCT was introduced to detect osteolytic lesions in the whole skeleton, with high accuracy, no need for contrast agents, and twofold to threefold lower radiation dose exposure compared with standard CT.[17,18] Low-dose whole-

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body CT has increased sensitivity compared with conventional skeletal survey in the detection of bone disease, which can reveal information leading to changes in therapy and disease management that could prevent or delay the onset of clinically significant morbidity and mortality as a result of skeletal-related events.[16]

- 18F-FDG PET/CT imaging could identify sites of extra-medullary disease (EMD), which represent an unfavorable prognostic feature, and it helps to accurately differentiate between solitary plasmacytoma (SP) and MM, as well as to predict the risk of early progression from smoldering MM (SMM) to active disease. This is more sensitive than CT for the detection of extra medullary disease. The combination of functional imaging with positron emission tomography (PET) plus morphological assessment with CT makes this technique the most effective in identifying potential sites of EMD.[19] The use of FGD PET/CT can also confirm a suspected diagnosis of solitary plasmacytoma and can distinguish between smoldering and active multiple myeloma. Thus, NCCN stated that FDG PET/CT is the preferred imaging for initial diagnostic workup.[1]
- Whole-body MRI can distinguish between smoldering and active multiple myeloma, acting as a problem-solving tool when PET/CT or whole-body CT is inconclusive.[1]
- MRI is the elective imaging technique to assess the degree of BM PC infiltration, even before bone destruction is present, owing to its ability to visualize large volumes of BM.[7] MRI is highly sensitive for the detection of bone and bone marrow focal lesions and predictive of progression. Unlike CT and PET/CT, MRI can detect focal bone lesions that are not yet lytic (i.e., without advanced cortical bone destruction). Up to half of individuals without other evidence of end-organ damage with normal plain films may demonstrate tumor-related lesions on MRI.[21,22]
- Whole-body diffusion weighted MRI (DW-MRI), also known as MRI Bone Marrow Blood Supply, is a non-contrast study that covers from the vertex to the heels. Diffusion-weighted magnetic resonance imaging (DWI or DW-MRI) is the use of specific MRI sequences as well as software that generates images from the resulting data that uses the diffusion of water molecules to generate contrast in MR images. This produces images where the contrast between tissues is based on differences in the motion of water at a cellular level. As cellularity in marrow increases secondary either to disease or increased hematopoietic tissue, the amount of free water increases. The capability of WB DW-MRI to demonstrate both focal and diffuse marrow infiltration throughout the whole skeleton makes this extremely useful as a subjective tool for monitoring disease status and assessment of response.[23]

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Leukemias, Myelodysplasia and Myeloproliferative Neoplasms (ONC-26)

Guideline

Leukemias, Myelodysplasia and Myeloproliferative Neoplasms – General Considerations (ONC-26.1)
Acute Leukemias (ONC-26.2)
Chronic Myeloid Leukemias, Myelodysplastic Syndrome and Myeloproliferative Disorders (ONC-26.3)
Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) (ONC-26.4)
References (ONC-26)

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Leukemias, Myelodysplasia and Myeloproliferative Neoplasms – General Considerations (ONC-26.1)

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- Routine advanced imaging is not medically necessary for the evaluation and management of hairy cell leukemia in the absence of specific localizing clinical symptoms.[7,8]

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Acute Leukemias (ONC-26.2)

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- Imaging indications for acute lymphoblastic leukemia in adult individuals are identical to those for pediatric individuals. See: **Acute Lymphoblastic Leukemia (ALL) (PEDONC-3.2)** in the Pediatric and Special Populations Oncology Imaging Guidelines.
- Imaging indications for acute myeloid leukemia in adult individuals are identical to those for pediatric individuals. See: **Acute Myeloid Leukemia (AML) (PEDONC-3.3)** in the Pediatric and Special Populations Oncology Imaging Guidelines.

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Chronic Myeloid Leukemias, Myelodysplastic Syndrome and Myeloproliferative Disorders (ONC-26.3)

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- Routine advanced imaging is not medically necessary in the evaluation and management of chronic myeloid leukemias, myelodysplastic syndromes or myeloproliferative disorders in the absence of specific localizing clinical symptoms or clearance for hematopoietic stem cell transplantation.
- See: **Hematopoietic Stem Cell Transplantation (ONC-29)** for imaging guidelines related to transplant.
- For work-up of elevated blood counts, see: **Paraneoplastic Syndromes – General Considerations (ONC-30.3)**.

Evidence Discussion

It is not routinely recommended to utilize advanced imaging for chronic myeloid leukemia, myelodysplastic syndromes, and myeloproliferative disorders. In the interest of safety such that infectious and iatrogenic complications are assessed in a timely manner, these guidelines provide flexibility for approval of advanced imaging for specific localizing symptoms, and a separate guideline section for imaging related to stem cell transplantation.[6,12,13]

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Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL) (ONC-26.4)

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- PET imaging is not medically necessary in the evaluation of CLL/SLL with the exception of suspected Richter's transformation (see suspected transformation, below).
- CLL/SLL is monitored with serial laboratory studies. Routine advanced imaging is not medically necessary for monitoring treatment response or surveillance, except when initial studies reveal bulky disease involvement.
- Bulky disease is defined as lymph node mass >10 cm or spleen >6 cm below costal margin.

Indication	Medically Necessary Imaging Study
Initial Staging/Diagnosis	• Routine advanced imaging is not medically necessary for initial evaluation of asymptomatic individuals
For ANY of the following: • Bulky lymph node mass (>10 cm) • Splenomegaly >6 cm below costal margin • Presence of B symptoms • Progressive anemia and thrombocytopenia • Prior to planned systemic therapy	ANY or ALL of the following: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177)
Treatment Response	• For individuals with bulky nodal disease at diagnosis, CT with contrast of previously involved area(s) every 2 cycles of therapy • Routine imaging is not medically necessary for individuals without bulky nodal disease at diagnosis

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Indication	Medically Necessary Imaging Study
End of Therapy Evaluation	• For individuals with bulky nodal disease at diagnosis, CT with contrast of previously involved area(s)
Suspected Progression	ANY or ALL of the following: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of previously involved area(s)
Suspected transformation (Richter's) from a low-grade lymphoma to a more aggressive type based on one or more of the following: • New B symptoms • Rapidly growing lymph nodes • Extranodal disease develops • Significant recent rise in LDH above normal range	• PET/CT (CPT® 78815 or CPT® 78816)
Surveillance	For individuals with bulky nodal disease at diagnosis, every 6 months for two years, then annually: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of previously involved area(s) Routine imaging is not medically necessary for individuals without bulky nodal disease at diagnosis

Evidence Discussion

Suspected/Diagnosis (whenever applicable)

- Diagnosis is by flow cytometry and biopsy. No imaging is supported.[1]

Initial staging

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- Routine advanced imaging for CLL/SLL is not supported. However, in the interest of individual safety, to recognize mass effect as assess risk of tumor lysis syndrome prior to treatment, CT imaging of the chest, abdomen and pelvis are supported. CT Neck may be added if neck symptoms, per general oncology guidelines.[1,12,13]

Restaging

- Routine imaging is not supported unless there is bulky nodal disease, as noted in 'initial staging' section. For bulky nodal disease, treatment response imaging with CT is supported every 2 cycles or for signs and symptoms of disease progression.
- There are no data-supported benefits to routine monitoring with PET/CT, and PET/CT is significantly more radiation than CT alone. PET/CT is supported only for signs and symptoms of Richter's transformation to high grade lymphoma, where the diagnosis can be made without invasive procedure using this modality.[1]

Surveillance

- There is no benefit to advanced imaging for surveillance of individuals without bulky nodal disease at diagnosis, and there is a risk of increased radiation exposure and invasive pursuit of incidental findings. In individuals with bulky nodal disease at diagnosis, flexibility is provided for surveillance imaging every 6 months for 2 years to assess for mass effect or progression.[131]

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Guideline

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Non-Hodgkin Lymphomas – General Considerations (ONC-27.1)

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- Lymphoma is often suspected when individuals have any of the following:
  - Bulky lymphadenopathy (lymph node mass >10 cm in size), hepatomegaly or splenomegaly
  - The presence of systemic symptoms (fever, drenching night sweats or unintended weight loss of >10%, called “B symptoms”)
- Individuals with AIDS-related lymphoma should be imaged according to the primary lymphoma histology.
- See: **Castleman’s Disease (unicentric and multicentric) (ONC-31.11)** for guidelines covering Castleman’s disease.
- See: **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) (ONC-26.4)** for guidelines covering Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL).

Indication	Medically Necessary Imaging Study
• Biopsy proven lymphoma, or • Suspected lymphoma and any of the following: ◦ Bulky lymphadenopathy (LN mass >10 cm) ◦ Hepatomegaly ◦ Splenomegaly ◦ B symptom: Unexplained fever, drenching night sweats, unintended weight loss >10% total body weight	• CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast ◦ MRI without and with contrast for individuals who cannot tolerate CT contrast due to allergy or impaired renal function
Signs or symptoms of disease involving the neck	• CT Neck with contrast (CPT® 70491)
Signs or symptoms suggesting CNS involvement with lymphoma.	• MRI Brain without and with contrast (CPT® 70553) • See: **CNS Lymphoma (also known as Microglioma) (ONC-2.7)**

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Indication	Medically Necessary Imaging Study
Known or suspected bone involvement with lymphoma	• MRI without and with contrast of symptomatic or previously involved bony areas ◦ Bone scan is inferior to MRI for evaluation of known or suspected bone involvement with lymphoma
Determine a more favorable site for biopsy when a relatively inaccessible site is contemplated	• PET/CT (CPT® 78815 or CPT® 78816) ◦ PET/CT is not medically necessary for all other indications prior to histological confirmation of lymphoma
CAR-T cell therapy	Once before treatment and once 30-60 days after completion of treatment: • PET/CT (CPT® 78815 and CPT® 78816)

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Diffuse Large B Cell Lymphoma (DLBCL) (ONC-27.2)

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- Grey zone lymphomas, primary mediastinal B cell lymphomas, Grade 3 (high) follicular lymphoma, double-hit or triple-hit lymphomas, and primary cutaneous diffuse large B cell lymphoma should also be imaged according to these guidelines.

Indication	Medically Necessary Imaging Study
Initial Staging/ Diagnosis	ONE of the following: • PET/CT (CPT® 78815 or CPT® 78816) OR • CT Chest with contrast (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177)
Treatment response for all stage I, and stage II without extensive mesenteric disease	ANY of the following: • CT with contrast of previously involved area(s) may be approved every 2 cycles (6-8 weeks) of therapy • PET/CT (CPT® 78815 or CPT® 78816) after 3-4 cycles of chemotherapy (in lieu of CT or for inconclusive CT)
Treatment response for stage II WITH extensive mesenteric disease, and stages III-IV	ANY of the following: • CT with contrast of previously involved area(s) may be approved every 2 cycles (6-8 weeks) of therapy • PET/CT (CPT® 78815 or CPT® 78816) after 2-4 cycles of chemotherapy (in lieu of CT or for inconclusive CT)
End of Chemotherapy and/or Radiation Therapy Evaluation	ANY or ALL of the following: • PET/CT (CPT® 78815 or CPT® 78816) at the end of chemotherapy and again at the end of radiation • CT with contrast of previously involved area(s)

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Indication	Medically Necessary Imaging Study
Suspected Recurrence	ANY or ALL of the following: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of previously involved area(s) • PET/CT can be considered in rare circumstances (e.g., bone involvement).
Biopsy-proven recurrence	• PET/CT (CPT® 78815 or CPT® 78816)
CAR-T cell therapy	Once before treatment and once 30-60 days after completion of treatment: • PET/CT (CPT® 78815 or CPT® 78816)
Surveillance for ANY of the following: • All stages of DLBCL • Relapsed lymphoma • Primary mediastinal large B cell lymphoma • Primary cutaneous diffuse large B cell lymphoma	• Every 6 months for 2 years after completion of treatment: ◦ CT Chest with contrast (CPT® 71260) ◦ CT Abdomen and Pelvis with contrast (CPT® 74177) ◦ CT with contrast of previously involved area(s)

Evidence Discussion

Initial Staging

- These guidelines for initial staging align with NCCN and support either PET/CT or diagnostic CTs. Greater than 97% of DLBCL are FDG-avid, though it is not known to be more accurate than CT for DLBCL at initial staging. However, baseline PET may be useful for comparison, as end of treatment remission assessment with PET/CT is more accurate than CT alone in DLBCL.20

Restaging

- CT is supported by NCCN every 2 cycles for restaging. PET/CT is supported by NCCN for interim restaging after 3-4 cycles of therapy and at the end of

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chemotherapy and/or radiation for lower stage disease. For stage II with extensive mesenteric disease, stage III, and stage IV, NCCN supported PET/CT more frequently - after 2-4 cycles of therapy and at the end of therapy. PET/CT remains standard for remission assessment at end of therapy, where its accuracy is greater that CT alone for DLBCL .[1,14] Documentation of residual tissue at end of therapy is useful for monitoring for relapse, and as such diagnostic, contrast enhanced CT is supported if requested in addition to PET at end of therapy .[1,14]

- FDG avidity is prognostic for relapsed/refractory DLBCL and may have a role in patient selection for CAR-T therapy and to assess response, so is supported as a baseline before CAR-T and once 30-60 days after completion, to assess response and identify individuals who may be candidates for further salvage therapy .[1,14]

Surveillance

- The false-positive rate with PET scans for surveillance in various studies is 16%-20%, potentially leading to unnecessary investigations, radiation exposure, biopsies, expense, and anxiety.[3,13] Several small studies have failed to note an improvement in relapse detection with CT over clinical observation in DLBCL, however, there is no definitive standard for surveillance imaging with CT.[5,6] The majority of relapses occur in the first 2 years, and the NCCN supported CT imaging of involved areas and chest, abdomen, and pelvis every 6 months for the first two year. In the interest of individual- and provider-centricity, these guidelines align with the NCCN with respect to surveillance in DLBCL.[1]

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Follicular Lymphoma (ONC-27.3)

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- This section applies to follicular lymphomas with WHO grade of 1 (low) or 2 (intermediate) and primary cutaneous follicle center lymphoma. Grade 3 (high) follicular lymphomas should be imaged according to guidelines found in: **Diffuse Large B Cell Lymphoma (DLBCL) (ONC-27.2)**.

Indication	Medically Necessary Imaging Study
Initial Staging/Diagnosis	EITHER of the following:: • CT Chest with contrast (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177) OR • PET/CT (CPT® 78815)
For ANY of the following, if PET/CT has not yet been performed: • If radiation therapy is being considered for stage I or II disease • CT results lead to a plan for systemic therapy	• PET/CT (CPT® 78815 or CPT® 78816)
Treatment Response	• CT with contrast of previously involved area(s) every 2 cycles of therapy
End of Therapy Evaluation	ONE of the following may be approved: • PET/CT (CPT® 78815 or CPT® 78816) OR • CT Chest with contrast (CPT® 71260) and • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of previously involved area(s)

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Indication	Medically Necessary Imaging Study
Suspected Recurrence	ANY or ALL of the following may be approved: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of previously involved area(s)
Suspected transformation (Richter's) from a low grade lymphoma to a more aggressive type based on one or more of the following: • New B symptoms • Rapidly growing lymph nodes • Extranodal disease develops • Significant recent rise in LDH above normal range	• PET/CT (CPT® 78815 or CPT® 78816)
Surveillance for ANY of the following: • After completion of active treatment • On maintenance treatment • Observation without any treatment	For all stages, every 6 months for two years, then annually: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of previously involved area(s)
Surveillance of pediatric-type follicular lymphoma in adults	Routine advanced imaging is not medically necessary after complete response

Evidence Discussion

Initial Staging

Diagnostic quality CT with contrast or PET/CT may be used for initial staging. Clinical stage is modified in only 15-20% of individuals with use of PET/CT and results in a change in treatment in only 8% of individuals.1 A baseline PET/CT is useful for comparison for treatment response and to determine if further treatment intensification is necessary and is recommended if systemic therapy is planned. PET/CT is particularly important in the setting of localized disease with a plan for radiation therapy only to rule out any other systemic disease and to serve as a baseline for treatment response.[1,3,4,20]

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Restaging

PET/CT is of unclear utility for interim restaging, as interim PET/CT response shows no association with overall survival, thus conventional CT is supported.[21] PET/CT does identify individuals at risk of progression at end of induction therapy, where initial studies showed that 69% of individuals who were classified as not having complete remission on CT were re-classified as complete metabolic remission when staged with PET/CT at end of induction.[20] This increased sensitivity and specificity more accurately identifies individuals at risk of poor progression-free survival who may be candidates for consolidative therapy and prevents over and under-treatment. These results only apply to end of induction PET/CT.[1,4,20]

While PET/CT alone is not sufficient to diagnose transformation of follicular lymphoma to diffuse large B cell lymphoma, when clinical signs and symptoms and lab values suggest transformation, PET/CT can be useful to detect transformation. SUV >10 predicts aggressive lymphoma with 80% certainty and PPV increases at higher SUVs.[1,18] FDG avidity is also standard of care to select biopsy site in suspected transformation.[1,18]

Surveillance

There are little data on the role of surveillance imaging in indolent lymphomas including follicular lymphoma. The majority of relapses occur within the first 2 years post completion of therapy, and these guidelines align with the NCCN support of CT no more than every 6 months in the first two years and no more than annually following. Given that indolent lymphoma is considered a chronic condition, there is no endpoint for this imaging if requested .[1] The exception is pediatric-type follicular lymphoma, for which there is no survival benefit with detection of recurrence via surveillance imaging vs clinical detection; surveillance imaging is not supported in this population.[1,13] PET/CT surveillance is generally not supported, due to a false positive rate as high as 20%, with no documented survival benefit, and increased radiation, invasive procedures, anxiety and cost.[13]

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Marginal Zone Lymphomas (ONC-27.4)

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- MALT lymphomas in any location and primary cutaneous marginal zone lymphoma should also be imaged according to these guidelines.
- Splenic Marginal Zone Lymphoma is diagnosed with splenomegaly, peripheral blood flow cytometry and bone marrow biopsy. Splenectomy is diagnostic and therapeutic. PET scan is not routinely medically necessary prior to splenectomy.

Indication	Medically Necessary Imaging Study
Initial Staging/ Diagnosis	ANY or ALL of the following: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177)
EITHER of the following: • If radiation therapy is being considered for stage I or II disease • If systemic therapy is planned	• PET/CT (CPT® 78815 or CPT® 78816)
Treatment Response	• CT with contrast of previously involved area(s) every 2 cycles of therapy
End of Therapy Evaluation	ONE of the following: • CT with contrast of previously involved area(s) • PET/CT (CPT® 78815 or CPT® 78816)
Suspected Recurrence	ANY or ALL of the following: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of previously involved area(s)

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Indication	Medically Necessary Imaging Study
Suspected recurrence and ANY of the following: • Symptoms of end organ dysfunction • Clinically significant or progressive cytopenias • Bulky disease (single mass of ≥7 cm or ≥3 or more nodal sites 3 cm in diameter) • Steady or rapid progression	In addition to the CT imaging above: • PET/CT (CPT® 78815 or CPT® 78816)
Surveillance of all stages of nodal marginal zone lymphoma for any of the following: • After completion of active treatment • On maintenance treatment • Observation without any treatment	Every 6 months for two years, then annually: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of previously involved area(s)
Surveillance of all stages of extranodal marginal zone lymphoma	Advanced imaging is not routinely medically necessary for surveillance of asymptomatic individuals

Evidence Discussion

Initial Staging

Diagnostic, contrasted CT of chest, abdomen and pelvis is supported for all individuals to assess extent of disease. PET avidity of extranodal marginal zone lymphoma is unreliable, as only 50%-75% of these tumors are FDG avid.[4] A baseline PET/CT is

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useful for comparison for treatment response and to determine if further treatment intensification is necessary, and so is recommended if systemic therapy is planned. PET/CT is particularly important in the setting of localized disease with a plan for RT only, to rule out any other systemic disease and to serve as a baseline for treatment response.[1,3,4]

Restaging

There is no clear role for PET in interim restaging of marginal zone lymphoma; CT is supported every 2 cycles in alignment with NCCN. End of therapy PET/CT is supported to identify individuals without a complete metabolic response who are candidates for extended therapy, to prevent over- or under- treatment.[1,4]

Surveillance

There are little data on the role of surveillance imaging in indolent lymphomas including marginal zone lymphoma. Extranodal marginal zone lymphoma typically remains localized, and asymptomatic surveillance with advanced imaging is not supported.[19] The majority of relapses occur within the first 2 years post completion of therapy. These guidelines align with NCCN support of CT no more than every 6 months in the first two years and no more than annually following. Given that indolent lymphoma is considered a chronic condition, there is no endpoint for this imaging if requested.[1] PET/CT surveillance is not universally supported, due to a false positive rate as high as 20%, with no documented survival benefit, and increased radiation, invasive procedures, anxiety, and cost.[13] However, PET/CT is a supported imaging modality for specific circumstances of recurrence; NCCN supported PET/CT in recurrence when there are indications for treatment.[1]

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Mantle Cell Lymphoma (ONC-27.5)

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Indication	Medically Necessary Imaging Study
Initial Staging/Diagnosis	ONE of the following: • CT Chest with contrast (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177) OR • PET/CT (CPT® 78815 or CPT® 78816)
Treatment Response	• CT with contrast of previously involved area(s) every 2 cycles of therapy • PET/CT is not medically necessary for monitoring treatment response but can be considered in rare circumstances when CT did not show disease (e.g., bone).
End of Therapy Evaluation	ONE of the following: • CT with contrast of previously involved area(s) • PET/CT (CPT® 78815 or CPT® 78816)
Suspected Recurrence	ANY or ALL of the following: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of previously involved area(s) • PET/CT can be considered in rare circumstances (e.g., bone involvement).
Surveillance for all stages	Every 6 months for 2 years, and then annually: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of previously involved area(s)

Evidence Discussion

Initial Staging

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Diagnostic CT with contrast or PET/CT is supported. PET/CT is the preferred modality particularly when systemic therapy is planned, in order to prevent under treatment.[1,20]

Restaging

Interim restaging with PET/CT has not been shown to change outcomes, thus CT alone is supported every two cycles unless the sites of disease are only visible on PET/CT. However, PET/CT is supported at end of planned therapy as a lack of complete metabolic response may require maintenance treatment .[1]

Surveillance

Late relapses, as far as 15 years out, can occur with mantle cell lymphoma. The benefit of detection of with imaging vs clinical detection remains unclear, and some studies have shown no significant advantage in survival for relapses after first remission detected by surveillance imaging.[28] However, this is still an active point for discussion among treating providers, and the NCCN supported surveillance imaging with CT scan.[1,28] Given that most providers consider NCCN the standard of care, this guideline aligns with the more conservative NCCN recommended timeframe, to acknowledge this data while maintaining an individual- and provider-centric approach. Surveillance scanning with PET/CT has a positive predictive value of only 24% in this entity and is not supported.[1,28]

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Burkitt's Lymphomas (ONC-27.6)

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Indication	Medically Necessary Imaging Study
Initial Staging/Diagnosis	ANY or ALL of the following: • PET/CT (CPT® 78815 or CPT® 78816) • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177)
Treatment Response	• CT with contrast of previously involved area(s) every 2 cycles of therapy • PET/CT is not medically necessary for monitoring treatment response but can be considered in rare circumstances when CT did not show disease (e.g., bone).
End of Therapy Evaluation	ANY or ALL of the following: • PET/CT (CPT® 78815 or CPT® 78816) at the end of chemotherapy and again at the end of radiation • CT with contrast of previously involved area(s)
Suspected Recurrence	ANY or ALL of the following: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of previously involved area(s) • PET/CT can be considered in rare circumstances (e.g., bone involvement).
Surveillance	Every 6 months for 2 years after completion of treatment: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177)

Evidence Discussion

Initial Staging/Diagnosis

In alignment with NCCN, both diagnostic quality CT scan with contrast and PET/CT are supported in Burkitt's Lymphoma. Diagnostic, contrasted CT is helpful for clarifying

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node bulk (individual nodes vs conglomerates), anatomic relationships of bulky disease, abdominal and Waldeyer's ring involvement, as well as abdominal visceral involvement, all of which are relevant to treatment decisions and emergency management in Burkitt's lymphoma. Baseline metabolic activity is useful for comparison at end of therapy, where FDG avidity defines treatment response.[1,3]

Treatment Response

CT alone (rather than PET/CT) should be used to assess response between cycles, as complete response is not defined until completion of upfront therapy regimen. At the end of all planned upfront therapy a PET/CT is supported, even in addition to diagnostic contrasted CTs. Metabolic response at this time point determines whether therapy can be considered complete or whether local therapy or intensification of treatment will be necessary.[1,3,4]

Surveillance

The role of surveillance in Burkitt's Lymphoma is somewhat controversial. Clinically evident symptoms of recurrence develop quickly in this aggressive entity, and recurrence is as likely to be diagnosed based on symptoms as by surveillance imaging in some studies (Lynch 2014). PET/CT surveillance of Burkitt's Lymphoma is widely discouraged as it increases false positive findings, radiation exposure, and does not improve outcomes .[4,13] NCCN is considered the standard for care in the U.S. and NCCN supported CT with contrast every 6 months for 2 years, with which these guidelines align for an individual- and provider-centric approach. Relapse after 2 years is rare, imaging after this point for asymptomatic surveillance has not been shown to improve outcomes.[1,13]

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Lymphoblastic Lymphomas (ONC-27.7)

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- Individuals with lymphoblastic lymphoma (even those with bulky nodal disease) are treated using the leukemia treatment plan appropriate to the cell type (B or T cell). Imaging indications in adult individuals are identical to those for pediatric individuals. See: **Acute Lymphoblastic Leukemia (ALL) (PEDONC-3.2)** in the Pediatric and Special Populations Oncology Imaging Guidelines.

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T Cell Lymphomas (ONC-27.8)

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- Includes Peripheral T-Cell Lymphomas, Mycosis Fungoides/Sézary Syndrome, Anaplastic Large Cell Lymphoma (ALCL) including breast implant-associated ALCL, Angioimmunoblastic lymphoma, and Primary Cutaneous CD30+T Cell Lymphoproliferative Disorders

Indication	Medically Necessary Imaging Study
Initial Staging/ Diagnosis	ANY or ALL of the following: • PET/CT (CPT® 78815 or CPT® 78816) • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177)
T-cell lymphoma of nasal cavity, oropharynx, or nasopharynx	In addition to the imaging above: • MRI Orbits, Face, and Neck without and with contrast (CPT® 70543)
Breast implant-associated ALCL	In addition to the above initial staging studies: • Ultrasound Breast (CPT® 76641 or CPT® 76642) ◦ MRI Breast (CPT® 77049) for evaluation of inconclusive ultrasound findings
Treatment Response	Any ONE of the following after 3-4 cycles: • PET/CT (CPT® 78815 or 78816) or • CT Chest with contrast (CPT® 71260), and • CT Abdomen and Pelvis with contrast (CPT® 74177) and • CT with contrast of previously involved area(s)

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Indication	Medically Necessary Imaging Study
End of Therapy Evaluation	Any ONE of the following at the end of chemotherapy and again at the end of radiation therapy: • PET/CT (CPT® 78815 or CPT® 78816) or • CT Chest with contrast (CPT® 71260), and • CT Abdomen and Pelvis with contrast (CPT® 74177), and • CT with contrast of previously involved area(s)
Suspected Recurrence	ANY or ALL of the following: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of previously involved area(s) • PET/CT can be considered in rare circumstances (e.g., bone involvement).
Surveillance, all stages	Every 6 months for 2 years, then annually for 5 years: • CT Chest with contrast (CPT® 71260), CT Abdomen and Pelvis with contrast (CPT® 74177), and CT of previously involved areas

Evidence Discussion

Initial Staging

FDG PET/CT fusion (PET with attenuation CT) is valuable for initial staging as individuals with T-cell lymphoma often have extranodal disease, which may be missed on body area specific diagnostic CTs. Noncontiguous nodes, Waldeyer ring, and GI/liver involvement is also common in T-cell lymphomas and may be difficult to distinguish on PET/CT fusion studies alone, thus our guidelines support the use of diagnostic quality, contrasted CTs when requested to ensure correct staging and treatment stratification and prevent under- or over-treatment, in addition to PET/CT fusion imaging.[1,2,29]

Treatment Response

Modality for restaging should be determined by which studies best illustrated disease at initial staging. PET/CT fusion imaging or body area specific diagnostic quality, contrasted CTs are generally adequate for comparison to initial staging to assess response[2] after 3-4 cycles and again at end of chemotherapy and at end of radiation. Imaging prior to 3-4 cycles may result in over- or under-treatment, and thus is not supported.[1,2]

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Surveillance

There is no evidence illustrating an overall survival advantage in detection of relapse from imaging vs clinical detection, but data suggests better progression-free survival after second line treatment in individuals undergoing imaging surveillance.[13] Considering these perspectives and to align with NCCN, CT of viscera and all previously involved areas is supported every 6 months for 2 years, then annually for 5 years.[2] PET/CT surveillance is not supported as no survival improvement is noted with PET/CT surveillance, and it subjects individuals to increased radiation, increased costs, and increased risk of invasive procedures for incidental findings, as the false positive rate in this setting is as high as 20%.[13,20] CT is generally supported for suspected recurrence as well, with PET reserved for biopsy-proven recurrence, by the same rationale.

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Post-Transplant Lymphoproliferative Disorders (ONC-27.9)

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- Post-transplant lymphoproliferative disorder (PTLD) or viral-associated lymphoproliferative disorder can rarely occur following solid organ or hematopoietic stem cell transplantation, or in primary immunodeficiency. When reduction of immunosuppression is unsuccessful, these are often treated with chemoimmunotherapy similar to high-grade NHL.
- This section applies to Monomorphic (B-cell type) PTLD and Polymorphic PTLD.
- For Hodgkin-lymphoma subtype of PTLD, see: **Hodgkin Lymphomas (ONC-28)** for imaging recommendations.

Indication	Medically Necessary Imaging Study
Initial Staging/ Diagnosis	ANY or ALL of the following: • PET/CT (CPT® 78815 or CPT® 78816) • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177)
Treatment Response	ANY or ALL of the following after 4 weeks of reducing immunosuppression or every 2 cycles (6-8 weeks) of chemo/ immunotherapy: • CT Chest with contrast (CPT® 71260), and • CT Abdomen and Pelvis with contrast (CPT® 74177), and • CT with contrast of previously involved area(s)
End of Therapy Evaluation	ANY one of the following at the end of treatment: • PET/CT (CPT® 78815 or CPT® 78816) or • CT Chest with contrast (CPT® 71260), and • CT Abdomen and Pelvis with contrast (CPT® 74177), and • CT with contrast of previously involved area(s)
Suspected recurrence	• CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177)

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Indication	Medically Necessary Imaging Study
Surveillance	No advanced imaging for surveillance

Evidence Discussion

Initial staging

FDG PET/CT fusion (PET with attenuation CT) is valuable for initial staging as individuals with PTLD often have extranodal and/or multi-site disease, which may be missed on body area specific diagnostic CTs. Individuals with single sites of disease may be managed with local treatment alone, thus thorough assessment for systemic disease is essential to prevent under-treatment. Node bulk has prognostic value and is used for treatment stratification, and bulky masses vs noncontiguous nodes may be difficult to distinguish on PET/CT fusion studies alone. These guidelines thus support the use of diagnostic quality, contrasted CTs when requested in addition to PET/CT fusion imaging.[1,29]

Restaging

Restaging with CT is supported every 2 cycles of chemotherapy as is standard for most disease processes .[1] Median time to failure of reduction of immunosuppression as first line therapy, however, is only 45 days, so for individual safety these guidelines support earlier restaging in this scenario as soon as 4 weeks after reduction of immunosuppression.[22] Changing therapy based on interim PET/CT alone is not supported and thus our guidelines support CT alone for interim restaging, with biopsy for concerning findings).[1,3,4] These guidelines do support PET/CT at end of planned treatment to ensure a complete metabolic response. [1,3,4] Concurrent diagnostic CTs may be done in lieu of PET/CT if requested, but diagnostic CTs in addition to PET/CT fusion studies do not offer additional information in the setting of a complete metabolic response .[3,4]

Surveillance

Advanced imaging surveillance is not supported for PTLD.[1,13] Surveillance imaging has not been shown to improve outcomes for PTLD and it subjects individuals to increased radiation, increased costs, and increased risk of invasive procedures for incidental findings.[13] Surveillance is predominantly via EBV PCR.[1]

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Waldenström Macroglobulinemia or Lymphoplasmacytic Lymphoma (ONC-27.10)

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Indication	Medically Necessary Imaging Study
Initial Staging/Diagnosis	ANY or ALL of the following: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • PET/CT (CPT® 78815 or CPT® 78816)
Treatment Response	• CT with contrast of previously involved area(s) every 2 cycles of therapy
End of Therapy Evaluation	• CT with contrast of previously involved area(s)
Suspected Recurrence	ANY or ALL of the following: • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of previously involved area(s)
Surveillance	No advanced imaging for surveillance

Evidence Discussion

Initial Staging

NCCN supported contrasted CT of chest, abdomen, and pelvis.[14,17] PET/CT fusion is recommended equally with diagnostic CT by the NCCN.[14]

Restaging

NCCN supported contrasted, diagnostic quality CTs every 2 cycles of chemotherapy and at end of treatment to determine response and prevent under-treatment. Diagnostic, contrasted CTs of chest, abdomen, pelvis and previously involved areas are supported for suspected recurrence.[14,17] PET/CT is not consistently correlated with monoclonal

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protein response, which is the primary means of monitoring this entity and PET/CT is not recommended for restaging of this entity.[14,15,16]

Surveillance

Surveillance of lymphoplasmacytic lymphoma is based on laboratory monitoring of blood counts and chemistries, serum proteins, and immunoglobulins. There is no established role for imaging surveillance in this entity.[14,16]

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Hodgkin Lymphoma (ONC-28)

Guideline

Hodgkin Lymphoma – General Considerations (ONC-28.1)
Classical Hodgkin Lymphoma (ONC-28.2)
Nodular Lymphocyte – Predominant Hodgkin Lymphoma (ONC-28.3)
References (ONC-28)

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Hodgkin Lymphoma – General Considerations (ONC-28.1)

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- Lymphoma is often suspected when individuals have any of the following:
  - Bulky lymphadenopathy (lymph node mass >10 cm in size), hepatomegaly or splenomegaly
  - The presence of systemic symptoms (fever, drenching night sweats or unintended weight loss of >10%, called “B symptoms”)
- Individuals with AIDS-related lymphoma should be imaged according to the primary lymphoma histology.
- The **Deauville Criteria** are internationally accepted criteria, which utilize a 5-point scoring system for the FDG avidity of a Hodgkin's lymphoma or Non-Hodgkin's lymphoma tumor mass as seen on FDG PET.
  - Score 1: No uptake above the background
  - Score 2: Uptake ≤mediastinum
  - Score 3: Uptake >mediastinum but ≤liver
  - Score 4: Uptake moderately increased compared to the liver at any site
  - Score 5: Uptake markedly increased compared to the liver at any site
  - Score X: New areas of uptake unlikely to be related to lymphoma

Indication	Medically Necessary Imaging Study
• Biopsy proven lymphoma, or • Suspected lymphoma and any one of the following: ◦ Bulky lymphadenopathy (LN mass >10 cm) ◦ Hepatomegaly ◦ Splenomegaly ◦ B symptom: Unexplained fever, drenching night sweats, unintended weight loss >10% total body weight	• CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast ◦ MRI without and with contrast for individuals who cannot tolerate CT contrast due to allergy or impaired renal function
Signs or symptoms of disease involving the neck	• CT Neck with contrast (CPT® 70491)

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Indication	Medically Necessary Imaging Study
Signs or symptoms suggesting CNS involvement with lymphoma	• MRI Brain without and with contrast (CPT® 70553) • See: **CNS Lymphoma (also known as Microglioma) (ONC-2.7)**
Known or suspected bone involvement with lymphoma	• MRI without and with contrast of symptomatic or previously involved bony areas ◦ Bone scan is inferior to MRI for evaluation of known or suspected bone involvement with lymphoma
Determine a more favorable site for biopsy when a relatively inaccessible site is contemplated	• PET/CT (CPT® 78815 or CPT® 78816) ◦ PET/CT not medically necessary for all other indications prior to histological confirmation of lymphoma
CAR-T cell therapy	Once before treatment and once 30-60 days after completion of treatment: • PET/CT (CPT® 78815 or CPT® 78816)

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Classical Hodgkin Lymphoma (ONC-28.2)

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- This section applies to nodular sclerosis, mixed cellularity, lymphocyte-depleted and lymphocyte-rich subtypes of Hodgkin lymphoma.
- Pregnancy-specific considerations: US Abdomen (CPT® 76700) or MRI Abdomen without contrast (CPT® 74181) and MRI Pelvis without contrast (CPT® 72195) are medically necessary in lieu of PET/CT or CT imaging.

Indication	Medically Necessary Imaging Study
Initial Staging/Diagnosis	ANY or ALL of the following: • PET/CT (CPT® 78815 or CPT® 78816) • CT Neck with contrast (CPT® 70491) • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177)
Prior to initiation of therapy if one month or more has passed since previous PET/CT was performed	• PET/CT (CPT® 78815 or CPT® 78816)
Treatment Response	• PET/CT (CPT® 78815 or CPT® 78816) as frequently as every 2 cycles
End of Chemotherapy and/or Radiation Therapy Evaluation	• PET/CT (CPT® 78815 or CPT® 78816) at the end of chemotherapy and again at the end of radiation (at least 12 weeks after completion of radiation therapy)
Suspected or biopsy proven recurrence	ANY or ALL of the following: • CT Neck with contrast (CPT® 70491) • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of previously involved area(s) • PET/CT (CPT® 78815 or CPT® 78816) if suspected recurrence ≥3 months after completion of therapy

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Indication	Medically Necessary Imaging Study
Surveillance	ANY or ALL of the following, every 6 months for 2 years after completion of therapy: • CT Neck with contrast (CPT® 70491) • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of previously involved area(s) In addition to the above studies: • A single follow-up PET/CT at three months if end of therapy PET/CT shows Deauville 4 or 5 FDG avidity

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Nodular Lymphocyte – Predominant Hodgkin Lymphoma (ONC-28.3)

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Indication	Medically Necessary Imaging Study
Initial Staging/Diagnosis	ANY or ALL of the following: • PET/CT (CPT® 78815 or CPT® 78816) • CT Neck with contrast (CPT® 70491) • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177)
Treatment Response	• CT with contrast of previously involved areas as frequently as every 2 cycles
End of Chemotherapy and/or Radiation Therapy Evaluation	• PET/CT (CPT® 78815 or CPT® 78816) at the end of chemotherapy and again at the end of radiation (at least 12 weeks after completion of radiation therapy)
Suspected Recurrence	ANY or ALL of the following: • CT Neck with contrast (CPT® 70491) • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of previously involved area(s)
Biopsy proven recurrence	• PET/CT (CPT® 78815 or CPT® 78816)

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Indication	Medically Necessary Imaging Study
Suspected transformation (Richter's) from a low-grade lymphoma to a more aggressive type based on one or more of the following: • New B symptoms • Rapidly growing lymph nodes • Extranodal disease develops • Significant recent rise in LDH above normal range	• PET/CT (CPT® 78815 or CPT® 78816)
Surveillance	ANY or ALL of the following every 6 months for 2 years after completion of therapy: • CT Neck with contrast (CPT® 70491) • CT Chest with contrast (CPT® 71260) • CT Abdomen and Pelvis with contrast (CPT® 74177) • CT with contrast of previously involved area(s) In addition to the above studies: • A single follow-up PET/CT at three months if end of therapy PET/CT shows Deauville 4 or 5 FDG avidity

Evidence Discussion

Initial staging and Restaging

PET imaging is useful for staging, prognosis, and treatment stratification in all subtypes of Hodgkin Lymphoma. Staging with PET/CT rather than CT often confirms a higher stage of disease. While overall survival outcome is not clearly improved by staging/ restaging with PET/CT, stratification of treatment based on PET/CT benefits individuals by preventing over- and under-treatment. PET is thus supported for initial staging, re-staging every 2 cycles, and at the end of therapy. False-positive rates are elevated in the weeks following radiation, reaching up to 20%. Decisions based on scans done in close proximity to radiation may result in over-treatment. Therefore, PET/CT should not be performed until 12 weeks after completion of radiation.[1,2,11]

Diagnostic CT with contrast is supported concurrently with PET/CT for initial staging as it may better differentiate nodal conglomerates from individual nodes in close

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proximity, and node bulk is prognostic and also used for treatment stratification. However, performing diagnostic CTs concurrently with PET/CT at restaging does not provide a benefit, as FDG avidity is highly indicative of response in Hodgkin lymphoma, where CT alone may over- or under- estimate response. FDG avidity guides response assessment and informs subsequent treatment decisions. This includes intensifying therapy if PET avidity persists after 2-4 cycles, or omitting consolidative radiotherapy in cases of good response on PET/CT after 4 cycles for low-stage disease. A complete metabolic response (Deauville score of 3 or less) should be confirmed to determine the end of treatment. If the end-of-therapy PET/CT shows a Deauville score of 4-5, repeating the PET/CT 3 months later is appropriate to confirm the metabolic status of residual masses and to prevent under-treatment.[1,2,11]

While PET/MRI shows high concordance with PET/CT at a decreased radiation dose, it is inferior for assessing disease in the lungs, more time-consuming, and more costly. Furthermore, it has not been established as a standard for treatment stratification in adult Hodgkin Lymphoma and is therefore not recommended over PET/CT.[6]

Surveillance

Surveillance imaging with PET/CT is not supported, as the false-positive rate with PET scans in this context is greater than 20%, leading to unnecessary investigations, radiation exposure, biopsies, expense, and individual anxiety. In addition, no statistically significant difference in survival has been noted with CT surveillance imaging in Hodgkin Lymphoma, despite a statistically significant increase in radiation exposure and cost. However, given that many existing protocols still require surveillance imaging, the NCCN continued to support CT surveillance every 6 months in the first two years post therapy if requested. Given that NCCN is viewed as the standard of care in most U.S. oncology treatment centers, this guideline aligns with this current NCCN recommendation for an individual- and provider-centric approach.[1,2,4]

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References (ONC-28)

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Hematopoietic Stem Cell Transplantation (ONC-29)

Guideline

General Considerations for Stem Cell Transplant (ONC-29.1)
Reference (ONC-29)

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General Considerations for Stem Cell Transplant (ONC-29.1)

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Transplant Types:

Allogeneic ("allo"): The donor and recipient are different people, and there are multiple types depending on the source of the stem cells and degree of match between donor and recipient. This is most commonly used in diseases originating in the hematopoietic system, such as leukemias and lymphomas, and bone marrow failure syndromes or metabolic disorders. Common types are:

- Matched sibling donor (MSD or MRD): Donor and recipient are full siblings and HLA-matched
- Matched unrelated donor (MUD): Donor and recipient are HLA matched but not related to each other
- Cord blood: Donor stem cells come from frozen umbilical cord blood not related to the recipient, sometimes from multiple different donors at once
- Haploidentical transplant (haplo): Donor is a half-HLA match to the recipient, usually a parent

Autologous ("auto"): The donor and recipient are the same person. The process involves delivery of high dose chemotherapy that is ablative to the bone marrow, followed by an infusion of one's own harvested stem cells.

Allogeneic HSCT results in a much greater degree of immunosuppression than autologous HSCT because of the need to allow the new immune system to chimerize with the recipient's body. Immune reconstitution commonly takes more than a year for individuals who receive allogeneic HSCT, and individuals remain at high- risk for invasive infections until that has occurred.

Pre-Transplant Imaging in HSCT:

- Pre-transplant imaging in HSCT generally takes place within 30 days prior to transplant and involves a reassessment of the individual's disease status as well as infectious disease clearance.

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Indication	Medically Necessary Imaging Study
Immediate pre-transplant period	• CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) for ANY of the following: ◦ Any individual prior to undergoing allogeneic transplant ◦ New findings on chest x-ray ◦ New/worsening signs/symptoms of chest involvement • CT Sinus (CPT® 70486) for any clinical signs or symptoms • CT of other body areas is not indicated without clinical signs or symptoms of involvement
Assess cardiac function	• Echocardiogram (CPT® 93306, CPT® 93307 or CPT® 93308) ◦ MUGA scan (CPT® 78472) in specific circumstances, see: **Oncologic Indications for Cancer Therapeutics-Related Cardiac Dysfunction (CTRCD) (CD-12.1)** in the Cardiac Imaging Guidelines
Assess pulmonary function	• Pulmonary function tests
Assess primary disease status	• See disease-specific guidelines for end of therapy response assessment

Post-Transplant Imaging in HSCT:

- There are many common complications from HSCT, including infection, acute and chronic graft versus host disease (GVHD), hepatic sinusoidal obstruction syndrome, restrictive lung disease, among others.
- Disease response generally takes place at ~Day +30 (autos and some allos) or ~Day +100 (allos) post-transplant.

Indication	Medically Necessary Imaging Study
Assess known or suspected HSCT complications	• Site-specific imaging

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Indication	Medically Necessary Imaging Study
Suspected hepatic GVHD (elevated liver enzymes)	• Abdominal US (CPT® 76700 or CPT® 76705)
Suspected Bronchiolitis Obliterans Syndrome (BOS)	• CT Chest without contrast (CPT® 71250)
Assess primary disease status post-transplant	• See disease-specific guidelines for end of therapy evaluation and surveillance
Individuals receiving tandem auto transplants (2-4 autos back-to-back, spaced 6 to 8 weeks apart)	• Guideline recommended imaging repeated after each transplant

Evidence Discussion

Pre-Transplant imaging in Hematopoietic Stem Cell Transplant (HSCT)

This refers to imaging in the immediate pre-transplant period, approximately 30 days prior to anticipated HSCT. There is not a clear consensus for pre-transplant infectious screening with imaging, but a CT Chest and CT Sinus are supported for any clinical signs and symptoms of respiratory or sinus infection. NCCN does not support CT imaging for infection screening in asymptomatic individuals.[1] There are no clear data to support pre-transplant sinus imaging in adults; extrapolation from pediatric data shows no change in pre-transplantation management nor prediction of post-transplant sinusitis based on pre-transplant imaging of asymptomatic individuals.[2,3] Screening for infection of abdomen and pelvis with advanced imaging is not supported as it has not been shown to change management or outcomes yet increases cost and radiation exposure.[1,4] Echocardiogram is supported prior to transplant conditioning for all patients, to assure the safest possible dosing for cardiotoxic agents. MUGA scan is supported to supplement echocardiogram in individuals with a previous low ejection fraction (LVEF <50%).[5]

Post-Transplant imaging in HSCT

Timing of post-transplant disease restaging varies by disease process. Generally, repeat imaging follows the disease-specific guidelines for end of therapy evaluation and surveillance. For individuals receiving tandem auto transplants, disease-specific imaging can be repeated after each transplant. Imaging for post-transplant complications maximizes safety and allows for early intervention.

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Reference (ONC-29)

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Medical Conditions with Cancer in the Differential Diagnosis (ONC-30)

Guideline

Fever of Unknown Origin (FUO) (ONC-30.1)
Unexplained Weight Loss (ONC-30.2)
Paraneoplastic Syndromes (ONC-30.3)
References (ONC-30)

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Fever of Unknown Origin (FUO) (ONC-30.1)

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- FUO is defined as a persistent fever ≥101°F and ≥3 weeks with unidentified cause.
- While fever is a classic "B" symptom of advanced lymphoma, a cancer-related fever presenting in isolation without any other signs or symptoms of neoplastic disease is rare.

Indication	Medically Necessary Imaging Study
If physical examination, Chest x-ray, and laboratory studies are non-diagnostic	• Echocardiogram (CPT® 93306) • Abdominal ultrasound (CPT® 76700) • MRI Brain without and with contrast (CPT® 70553)
Above studies (including PE/ENT exam, pelvic exam, and DRE with laboratory studies) have failed to demonstrate site of infection	• CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast • Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s): CPT® 78800, CPT® 78801, or CPT® 78802, CPT® 78804, CPT® 78803 or CPT® 78831 (SPECT), or CPT® 78830, or CPT® 78832 (SPECT/CT)
"B" symptoms	• See: **Non-Hodgkin Lymphomas (ONC-27)**
Any CNS sign/symptom accompanied by fever	• MRI Brain without and with contrast (CPT® 70553)
All individuals	• PET is not indicated in the work-up of individuals with FUO

Evidence Discussion

The widely accepted definition of "Fever of Unknown Origin" is persistent fever of at least 101 degrees F for at least 3 weeks with unidentified cause. Most published recommendations are based on expert consensus rather than data. Malignancy accounts for 20%-30% of FUO in adults.[14,15] The remainder are infectious, inflammatory, and immune mediated. Physical exam, chest x-ray, and laboratory findings

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including workup for specific infections should guide workup, and all routine age-based cancer screening should be complete. If these are negative, further workup may be indicated. Echocardiogram, abdominal ultrasound, and MRI Brain without and with contrast are supported, with sensitivity rates of 80%-86%, as abdominal and pelvic abscess, endocarditis, and viral and bacterial CNS processes remain more common causes of fever than malignancy.[14,15,16,17] These modalities limit radiation exposure and are recommended as first line imaging in most algorithms.[14,15,16,17]

If the above workup has not demonstrated a source of infection, CT with contrast of the chest, abdomen and pelvis is supported as second line imaging, with sensitivity of up to 90% and specificity up to 70% for determining the cause of fever.[14,15] Technitium-based scans are insensitive but highly specific (93%-94%), with the advantage of lower radiation exposure than CT, and are supported to localize infectious or inflammatory foci.[14,18,21] MRI Brain without and with contrast is supported for any CNS symptoms accompanied by fever, as supported by several FUO algorithms and as outlined in HD-14.1 CNS and Head Infection. B symptoms with concern for lymphoma also warrant CTs, with further details outlined in EviCore ONC-27.1. The utility of PET/CT in workup of FUO is emerging, but specificity is variable, ranging from 52%-85%.[16,17,19-22] At this time it is not routinely supported in the workup of FUO.

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Unexplained Weight Loss (ONC-30.2)

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- Unintentional weight loss is defined as loss of ≥10 lbs. or ≥5% of body weight over 6 months or less, without an identifiable reason.
- Initial workup for all individuals may include appropriate detailed history, physical exam, baseline laboratory studies (e.g., CBC, CMP, HgbA1c, ESR/CRP, infectious workup, stool hemoccult, endocrine evaluation to rule out thyroid, pituitary, or gonadal dysfunction, etc.), chest x-ray, age-appropriate cancer screening, and neurological evaluation to rule out depression/dementia.
- Additional workup is directed to evaluate specific signs, symptoms, red flags, or abnormalities detected on initial workup. See condition-specific imaging guidelines for additional details.
- PET is not medically necessary in the work-up of individuals with unexplained weight loss.

Indication	Medically Necessary Imaging Study
CNS symptoms or abnormal pituitary hormones	• MRI Brain or Sella Turcica without and with contrast (CPT® 70553)
Abnormal thyroid function	• Thyroid ultrasound (CPT® 76536)
Abnormal liver function	• Abdominal ultrasound (CPT® 76700)
Abnormal kidney function	• Ultrasound Kidney and Bladder (CPT® 76770 or CPT® 76775)
Suspected cardiac dysfunction	• Echocardiogram (CPT® 93306)
Non-smokers	• Chest x-ray ◦ CT Chest with contrast (CPT® 71260) to evaluate abnormalities on chest x-ray
Current or former smokers	• CT Chest with contrast (CPT® 71260)
Dysphagia or early satiety	See: **Dysphagia and Esophageal Disorders (NECK-3)**
GI bleeding	See: **GI Bleeding (AB-22)**

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Indication	Medically Necessary Imaging Study
Abdominal pain without red flag signs	See: **Abdominal Pain (AB-2)**
Suspected pancreatic cancer in individuals aged ≥60 years with weight loss and at least one of the following[13]: • Diarrhea • Back pain • Abdominal pain • Nausea/vomiting • Constipation • New onset diabetes • Abnormal labs (CA 19-9, LFTs) • Non-diagnostic or negative abdominal ultrasound	Any ONE of the following: • CT Abdomen with contrast (CPT® 74160) • CT Abdomen and Pelvis with contrast (CPT® 74177) • MRI Abdomen without and with contrast (CPT® 74183) See also: **Epigastric Pain and Dyspepsia (AB-2.5)**
If all of the above do not identify cause of weight loss	Any of the following, if not previously performed: • CT Chest (CPT® 71260) • CT Abdomen and Pelvis (CPT® 74177) with contrast

Evidence Discussion

Gradual weight loss is a common occurrence in the elderly. Unintentional weight loss that is associated with in increased risk of morbidity and mortality is generally defined as a weight loss of 5% body weight over a period of 6-12 months.[23,26] Among individuals with unintentional weight loss, a minority are diagnosed with malignancy.[24,25] There is no unified published consensus or guideline to guide the workup for weight loss, but most publications recommend that the primary workup should be symptom-focused and include laboratory studies and age-appropriate cancer screening. Workup for particular symptoms or lab findings should be guided by condition-specific guidelines. Based on symptoms and lab findings, thyroid ultrasound, abdominal/renal ultrasounds, and/or echocardiogram are supported by these guidelines. All individuals with CNS symptoms or abnormal pituitary hormones warrant an MRI. A chest x-ray is reasonable in all individuals.[23,26,27]

A negative baseline evaluation is reassuring; with at least one prospective study showing that no individuals with a negative baseline clinical and laboratory evaluation were found to have malignancy on subsequent studies.[23,27] However, other prospective studies do illustrate that underlying malignancy may be detected on advanced imaging,

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with the highest predictive value for lung, pancreatic, lymphomas, prostate and colorectal cancers.[24,25] Based on this, these guidelines support contrasted CT Chest as part of initial workup for all smokers with clinically significant weight loss. These guidelines also support CT or MRI Abdomen (or CT Abdomen and Pelvis) as part of initial workup for individuals age 60+ with clinically significant weight loss and additional signs and symptoms significantly associated with pancreatic cancer.[13] For all other individuals, if the individuals have clinically significant unintentional weight loss as defined in paragraph 1, and the initial baseline evaluations above are negative, CT with contrast of the chest, abdomen, and pelvis are appropriate and supported by these guidelines.[23,24,26]

No published algorithm routinely supports PET/CT in the evaluation of unexplained weight loss, and there are no prospective studies illustrating the sensitivity or specificity of PET in this scenario. There may be individuals who meet evidence-based criteria for PET/CT based on their specific signs, symptoms and findings, particularly in the lymphomas (refer to guidelines ONC-27, ONC-28, and ONC-1.4).

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Paraneoplastic Syndromes (ONC-30.3)

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- Paraneoplastic syndromes are metabolic and neuromuscular disturbances. These syndromes are not directly related to a tumor or to metastatic disease. There may be a lead time between initial finding of a possible paraneoplastic syndrome and appearance of the cancer with imaging. Limited studies suggest annual imaging for 2 years after diagnosis of possible paraneoplastic syndrome may detect cancer, however benefit after 2 years is not well documented.
- The following are the most common symptoms of paraneoplastic syndromes known to arise from various malignancies:
  - Hypertrophic Pulmonary Osteoarthropathy: Often presents as a constellation of rheumatoid-like polyarthritis, periostitis of long bones, and clubbing of fingers and toes
  - Amyloidosis
  - Hypercalcemia
  - Hypophosphatemia
  - Cushing's Syndrome
  - Somatostatinoma syndrome (vomiting, abdominal pain, diarrhea, cholelithiasis)
  - Syndrome of inappropriate antidiuretic hormone secretion (SIADH)
  - Polymyositis/dermatomyositis
  - Opsoclonus
  - Paraneoplastic sensory neuropathy
  - Subacute cerebellar degeneration
  - Eaton-Lambert syndrome (a myasthenia-like syndrome)
  - Second event of unprovoked thrombosis
  - Disseminated Intravascular Coagulation
  - Migratory thrombophlebitis
  - Polycythemia
  - Chronic leukocytosis and/or thrombocytosis
  - Elevated tumor markers
  - Cryptogenic stroke (see also: **HD-21.3)**
- See: **Muscle Disorders (PN-6)** in the Peripheral Nerve Disorders Imaging Guidelines.
- See: **Multiple Myeloma and Plasmacytomas (ONC-25)** for evaluation of possible multiple myeloma.

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Indication	Medically Necessary Imaging Study
Initial evaluation	• CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast
ANY of the following: • Abnormality on conventional imaging difficult to biopsy • Inconclusive conventional imaging • Documented paraneoplastic antibody and conventional imaging fails to demonstrate primary site	• PET/CT (CPT® 78815 or CPT® 78816)
Subsequent evaluation for known paraneoplastic syndrome	• CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast every 6 months for 2 years after initial imaging for Lambert-Eaton Myasthenia syndrome • CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast every 6 months for 4 years for all other paraneoplastic syndromes
Systemic mastocytosis	ANY ONE of the following: • CT Abdomen and Pelvis (CPT® 74177) with contrast • MRI Abdomen (CPT® 74183) and MRI Pelvis (CPT® 72197) without and with contrast • PET/CT scan is not medically necessary for evaluation of mastocytosis
First episode of unprovoked DVT/VTE	• Imaging to evaluate for malignancy is not medically necessary
Second unprovoked DVT/PE	• Imaging may be considered in the setting of a negative work-up for inherited thrombophilia and antiphospholipid syndrome
Thyroid US is recommended for elevated CEA, and upper/lower endoscopy is recommended for elevated CEA or CA 19-9.	

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Evidence Discussion

Cross-sectional imaging with contrasted CT of the chest, abdomen and pelvis is generally considered first-line to look for visceral malignancy in most paraneoplastic syndromes. While sensitivity varies widely (30%-82% across studies), specificity is reasonable (71%-100%).[33] PET/CT is supported in individuals with documented paraneoplastic antibodies, inconclusive conventional imaging, or to assess for alternate biopsy sites when an abnormality is found on conventional imaging that is inaccessible for biopsy. The sensitivity and specificity of PET/CT is approximately 80%, when used to evaluate individuals who had negative or unclear conventional imaging.[29] PET/CT is not supported as first line imaging as PET may miss smaller tumors, and has a false negative rate of approximately 20% in this setting .[33] While there is a lack of prospective data on monitoring paraneoplastic syndromes, it is known that these phenomena may precede detectable malignancy. In the interest of individual safety, these guidelines support repeat CT imaging every 6 months for 4 years; for Lambert-Eaton Syndrome, 2 years is sufficient as 96% of associated SCLC is detected in the first year, with later reports generally from an era of lesser quality CTs.[30,31,34]

Venous thromboembolism in the absence of a hypercoagulable risk factor may suggest occult malignancy. Blood testing, exam and non-advanced imaging have been shown to be helpful in most cancers that present with a first unprovoked DVT, but other advanced imaging is not cost-effective without other symptoms suggesting malignancy in this setting. In the setting of a second unprovoked DVT, cross-sectional imaging with contrasted CT may be considered and is supported by these guidelines.[31,35,36]

Systemic mastocyctosis may also develop extramedullary involvement and end-organ dysfunction, particularly involving liver and spleen. CT or MRI of abdomen and pelvis are supported in alignment with NCCN. There is no NCCN recommendation for PET/CT in systemic mastocytosis.

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Metastatic Cancer, Carcinoma of Unknown Primary Site, and Other Types of Cancer (ONC-31)

Guideline

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General Guidelines (ONC-31.0)

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- Guideline sections Lung Metastases (ONC-31.1) through Spinal Vertebral Metastases (ONC-31.6) are designed to supplement the disease-specific guidelines when the disease-specific guidelines do not provide guidance on the clinical scenario in question.
- These sections can also be used if the cancer type is rare and does not have its own diagnosis-specific imaging guidelines.
- These sections may also be used for lesions suspicious for cancer that do not have guidance in other disease-specific areas of the guidelines.

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Lung Metastases (ONC-31.1)

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Indication	Medically Necessary Imaging Study
New or worsening signs or symptoms suggestive of metastatic lung involvement or new or worsening chest x-ray abnormality	• CT Chest with contrast (CPT® 71260) • CT Chest without contrast (CPT® 71250) if there is a contraindication to CT contrast or only parenchymal lesions are being evaluated
Chest wall or brachial plexus involvement	• MRI Chest without and with contrast (CPT® 71552)
ONE of the following **and** no diagnosis-specific guideline regarding PET imaging: • Lung nodule(s) ≥8 mm • Confirm solitary metastasis amenable to resection on conventional imaging	• PET/CT (CPT® 78815) • When primary cancer known, PET request should be reviewed by primary cancer guideline
Previous or current malignancy and pulmonary nodule(s) that would reasonably metastasize to the lungs	• CT Chest with contrast (CPT® 71260) or CT Chest without contrast (CPT® 71250) at 3, 6, 12, and 24 months from the first study

Evidence Discussion

All individuals with a history of cancer who have new signs or symptoms suggestive of metastatic disease to the lung, or who have new or worsening findings on chest x-ray, warrant CT Chest. Contrast is preferable in most scenarios to include evaluation of soft tissue and nodes, but a non-contrast study may be approved if there is a contraindication to contrast or if only parenchymal lung lesions are being evaluated. CT with contrast (or without if for parenchymal lesion only) is supported to follow up new lung nodules in individuals with a history of malignancy.[55] There is, however, no clear consensus on a timeline for this follow up across all malignancy types. Where guidance is not provided in the disease-specific guidelines, these guidelines suggest a follow up timeline of CT at 3, 6, 12, and 24 months from discovery of nodule, extrapolating from Fleischner and Lung-RADS data that a nodule stable >24 months is exceedingly unlikely to be malignant.[54,55] MRI with and without contrast is supported for suspected malignant infiltration of the brachial plexus or chest wall infiltration, for better soft tissue delineation.[52,53]

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PET/CT is generally addressed in the guidelines for each specific cancer. If no specific guidance is provided, PET/CT is supported for lung nodules greater than or equal to 8mm.[54] In the interest of safety to prevent futile invasive procedures on individuals with occult metastatic disease, PET/CT is also supported by these guidelines to confirm solitary metastasis on conventional imaging that may be amenable to curative-intent resection. PET/CT surveillance is not generally supported due to high radiation exposure, financial toxicity, and excess radiation exposure.

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Liver Metastases (ONC-31.2)

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- Yitrium-90 Radioembolization (Y90-RE) is also known either as Selective Internal Radiation Therapy (SIRT) or trans-arterial radioembolization (TARE). Y90-RE is medically necessary for inoperable hepatocellular carcinoma and metastatic disease to the liver. Yitrium-90 resin or glass microsphere is injected into the hepatic vessel which supplies the tumor bed. This delivers high radiation dose to the tumor selectively.
- Yitrium-90 Radioembolization consists of three parts:

1. The pre-treatment planning angiogram with Technetium 99m macroaggregated albumin (Tc-MAA). The Tc-MAA acts as surrogate for biodistribution of application of Y-90. Planar or SPECT/CT are performed for calculation of lung shunt fraction and identification of extra hepatic uptake. The assessment of hepatopulmonary shunt is important in the determination eventual radiation dose. Presence of extra-hepatic uptake may preclude treatment or require coil embolization.
2. Yitrium-90 Radioembolization treatment typically done 7-10 days after mapping.
3. Post-treatment imaging may be done to confirm tumor localization.

- Ablation of liver metastases or primary HCC may be performed utilizing chemical, chemotherapeutic, radiofrequency, or radioactive isotope. Regardless of the modality of ablation, PET is not medically necessary for assessing response to this mode of therapy.

Indication	Medically Necessary Imaging Study
New or worsening signs or symptoms suggestive of metastatic liver involvement or new elevation in LFTs	• CT Abdomen with (CPT® 74160) or without and with (CPT® 74170) contrast
ANY of the following: • Considering limited resection • Inconclusive CT findings	• MRI Abdomen without and with contrast (CPT® 74183)

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Indication	Medically Necessary Imaging Study
ONE of the following **and** no diagnosis-specific guideline regarding PET imaging: • Confirm solitary metastasis amenable to resection on conventional imaging • LFT's and/or tumor markers continue to rise and CT and MRI are negative	• PET/CT (CPT® 78815) ◦ When primary cancer known, PET request should be reviewed by primary cancer guideline
Monitoring of liver metastases that have been surgically resected	• Review according to primary cancer guideline
Evaluation of hepatic artery chemotherapy infusion or TACE (transarterial chemoembolization)	• CTA Abdomen (CPT® 74175) immediately prior to embolization ONE of the following studies immediately prior to and one month post-embolization, if not previously done: • CT Abdomen without and with contrast (CPT® 74170) • MRI Abdomen without and with contrast (CPT® 74183)

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Indication	Medically Necessary Imaging Study
Evaluation for hepatic artery radioembolization with Y-90 radioactive spheres (TheraSphere or SIR Spheres) for liver metastases or primary liver tumors	To assess hepatic vascular anatomy before the procedure, any ONE of the following: • 3D Rendering (CPT® 76377) if conventional hepatic angiogram is being performed • CTA Abdomen (CPT® 74175) ONE of the following studies PRE-treatment based upon provider preference: • Radiopharmaceutical Localization Limited Area (CPT® 78800 or CPT® 78801) • SPECT or SPECT/CT (CPT® 78803, 78831, 78830, or 78832) • CPT® 78835 may be approved as an add-on code with SPECT/CT codes only (CPT® 78803, 78831, 78830, or 78832) for calculation of lung shunt fraction if planar imaging (CPT® 78800 or CPT® 78801) not performed. Liver-lung shunt calculation is included in planar scans and does not require additional Lung Perfusion Scan ONE of the following studies POST-treatment based upon provider preference: • Radiopharmaceutical Localization Limited Area (CPT® 78800 or CPT® 78801) • SPECT or SPECT/CT (CPT® 78803, 78831, 78830, or 78832)
Monitoring of ablated liver metastases or primary tumors	ONE of the following, immediately prior to ablation, 1 month post-ablation, then every 3 months for 2 years, and then every 6 months until year 5: • CT Abdomen without and with contrast (CPT® 74170) • MRI Abdomen without and with contrast (CPT® 74183)

Evidence Discussion

For individuals with known malignancy with new symptoms suggestive of metastatic liver involvement or increase in LFTs, these guidelines support CT of the abdomen

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with contrast or without and with contrast as first line imaging. This helps differentiate vascular enhancement patterns, number of lesions, and associated abdominal findings. If the CT remains indeterminate, MRI without and with contrast is supported as MRI enables better characterization of the internal features of the lesion.[56,57] For safety, MRI is also supported if limited resection is being considered.

PET/CT is less specific than conventional imaging for liver lesions, and is not first line to clarify indeterminate liver findings on CT.[56] However, if LFTs or tumor markers continue to rise and CT and MRI are negative, PET/CT may be used as a problem-solving tool to look for occult metastatic disease.[56] In the interest of safety, if a curative-intent resection of a liver lesion is planned, PET/CT may be used to confirm the liver metastasis is solitary to prevent subjecting the individual to a futile resection.

Imaging is medically necessary to evaluate for hepatic artery chemotherapy infusion or transarterial chemoembolization (TACE). Either CT or or MRI with and without contrast may be used for this purpose, per provider preference based on individual tumor characteristics, per the logic noted in paragraph 1. These guidelines for imaging for radioembolization align with international working group TheraSphere Global Dosimetry Steering Committee (DSC) recommendations.[59] Vascular mapping prior to radioembolization with CTA abdomen (with 3D rendering if requested), as well as a single nuclear medicine liver planar study or SPECT/SPECT-CT study, based on provider preference and individual tumor characteristics.[59] Liver-lung shunt calculations can generally be calculated from pre-treatment scans and an addition lung perfusion scan is not generally supported.[59] The nuclear imaging used pre-treatment is supported once post-treatment, and cross-sectional imaging with CT or MRI to evaluate response is supported 1 month post treatment.[59]

Monitoring of ablated liver tumors, metastatic or primary, is with cross sectional imaging with CT or MRI Abdomen, with and without contrast, per provider preference based on individual and tumor characteristics. In alignment with NCCN hepatocellular carcinoma surveillance recommendations, this guideline supports this imaging 1 month post ablation, every 3 months for 2 years, then every 6 months until year 5.[58] PET is not routinely supported for follow up for ablated liver lesions, regardless of ablation modality.[58,60] The sensitivity of PET is only 65% in this setting, compared with 96% for MRI, and the positive and negative predictive values are also significantly superior for MRI vs PET.[60]

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Brain Metastases (ONC-31.3)

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Indication	Medically Necessary Imaging Study
Individual with cancer and signs or symptoms of CNS disease or known brain metastasis with new signs or symptoms.	• MRI Brain without and with contrast (CPT® 70553)
To determine candidacy for SRS, and a diagnostic thin-slice MRI Brain has not been performed in the preceding 30 days	• MRI Brain without and with contrast (CPT® 70553)
Stereotactic radiosurgery planning	• Unlisted MRI for treatment planning purposes (CPT® 76498)
Monitoring of brain metastases treated with surgery or radiation therapy	Post-treatment, then every 3 months for 1 year and every 4 months thereafter: • MRI Brain without and with contrast (CPT® 70553) ***Individuals treated with stereotactic radiosurgery alone may have MRI Brain without and with contrast (CPT® 70553) immediately after stereotactic radiosurgery, then every 2 months for the first year, and then every 6 months thereafter
Brain metastases treated with radiation therapy, with recent MRI Brain indeterminate in distinguishing radiation necrosis vs. tumor progression	• MRI Perfusion imaging (CPT® 70553)

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Indication	Medically Necessary Imaging Study
Brain metastases treated with radiation therapy, with recent MRI Brain and MR Perfusion studies both unable to distinguish radiation necrosis vs. tumor progression	• PET Metabolic Brain (CPT® 78608)
Any of the following: • Solitary brain metastasis suspected in individual with prior diagnosis of cancer and no diagnosis-specific guideline regarding PET imaging • Brain metastases and no known primary tumor	• CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast • Mammography for female individuals • PET/CT (CPT® 78815 or CPT® 78816) for ANY of the following: ◦ Inconclusive conventional imaging ◦ Confirm either stable systemic disease or absence of other metastatic disease ◦ When primary cancer known, PET request should be reviewed by primary cancer guideline
Primary brain tumors	See: **Primary Central Nervous System Tumors (ONC-2)**
MR Spectroscopy (CPT® 76390) is not medically necessary for evaluation of metastatic brain cancer	

Evidence Discussion

Brain metastases are the most common malignant intracranial tumors with an incidence 10-fold higher than primary central brain tumors. Common presenting signs and symptoms of brain metastases include headache, nausea, vomiting, focal neurologic deficits, and mental status changes. The most common cancer associated with brain metastases is lung cancer approaching 50% of the cases. Melanoma is associated with the highest incidence of brain metastases.

These guidelines support MRI Brain without and with contrast as the standard imaging modality for evaluation of an individual with suspected or known brain metastases. The post-treatment monitoring after surgery or radiation is based on NCCN guidelines. Specifically for stereotactic radiosurgery planning, a diagnostic MRI is not supported and the MRI request is based on an unlisted procedure code. Advanced imaging with MR perfusion imaging is a problem-solving tool, complementing a standard MRI Brain, to distinguish between radiation necrosis and tumor progression. PET Metabolic Brain

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imaging is a useful tool to distinguish between radiation necrosis and tumor progression with recent indeterminate MRI Brain and MR Perfusion study.

In individuals who present with brain metastases and no known primary tumor, an evaluation to define a primary cancer is supported. Imaging studies that are supported include CT Chest and CT Abdomen and Pelvis with contrast. Mammography is supported for this staging in female individuals. PET/CT is indicated for inconclusive standard imaging, for evaluation of other metastatic disease or for staging if supported by primary cancer guideline. Biopsy or resection of a suspicious lesion is needed to establish a definitive diagnosis.

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Adrenal Gland Metastases (ONC-31.4)

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Indication	Medically Necessary Imaging Study
Differentiate benign adrenal adenoma from metastatic disease	• See: **Adrenal Cortical Lesions (AB-16.1)** in the Abdomen Imaging Guidelines
Known cancer and no known systemic metastases: • New adrenal mass • Enlarging adrenal mass • Inconclusive findings on recent CT	If not done previously, ANY of the following: • CT Abdomen without contrast (CPT® 74150) • CT Abdomen without and with contrast (CPT® 74170, adrenal protocol) • MRI Abdomen without contrast (CPT® 74181) • MRI Abdomen without and with contrast (CPT® 74183) • CT-directed needle biopsy (CPT® 77012)
One of the following and no diagnosis-specific guideline regarding PET imaging: • Biopsy is not feasible or is non-diagnostic • Isolated metastasis on conventional imaging and individual is a candidate for aggressive surgical management	• PET/CT (CPT® 78815) When primary cancer known, PET request should be reviewed by primary cancer guideline
Known extra-adrenal malignancy and undiagnosed adrenal mass being monitored off treatment	See: Phases of **Oncology Imaging and General Phase-Related Considerations (ONC-1.2)**

Evidence Discussion

In individuals with known extra-adrenal malignancy and no known systemic metastatic disease who have been found to have a new, enlarging or inconclusive adrenal mass on other imaging, a non-contrast CT adrenal protocol or CT Abdomen with and without

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contrast adrenal protocol or an MRI Abdomen without or without and with contrast are all supported by ACR appropriateness criteria.[62] Non-contrast images allow for initial attenuation measurements, but contrast-enhanced images with imaging for washout characteristics can help differentiate adenomas from metastatic disease.[7,62] Non-contrast chemical shift MRI can help detect intracytoplasmic fat, providing insight into benign vs malignant characteristics, but post-contrast imaging adds further specificity for adenoma.[7,62] CT-directed needle biopsy may also be appropriate and is supported by the guidelines if requested.[7,62]

The utility of PET/CT varies with histology and type of radiotracer. Generally, the use of PET/CT for a given malignancy is addressed in the disease-specific guidelines. For lesions with no known history of malignancy, there is no primary evidence supporting the use of FDG PET-CT for initial evaluation.[62] In one study of 1,049 incidental adrenal masses in individuals with no known history of cancer, zero were malignant.[27] Mild SUV uptake can also be seen in benign adenomas, bringing the sensitivity of PET/CT to only 85% .[28,29,62] False-positive interpretations potentially result in unnecessary invasive procedures. When other adrenal-specific cross sectional imaging is suspicious for malignancy by size and other criteria, biopsy is preferred. If a biopsy is not feasible or non-diagnostic, PET/CT may show increased SUV uptake in malignant lesions and guide further decision making, and is supported by the ACR in this context.[7,62]

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Bone (Non-Vertebral) Metastases (ONC-31.5)

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- This guideline may be used for individuals with or without a history of malignancy, depending on the indications as listed below.

Indication	Medically Necessary Imaging Study
Individuals ≥40 years of age with no history of malignancy who have a symptomatic bone lesion seen on x-ray and malignancy is suspected	EITHER of the following: • CT Chest with contrast (CPT® 71260), CT Abdomen and Pelvis with contrast (CPT® 74177), and Bone scan (CPT® 78306) OR • FDG PET/CT (CPT® 78815 or CPT® 78816)
Individuals less than 40 years of age with a bone lesion on x-ray	See: **Lesion of Bone (MS-10.2)**
Suspected bone metastasis due to ANY of the following in an individual with a current or prior malignancy: • Bone pain • Rising tumor markers • Elevated alkaline phosphatase	• Bone scan (CPT® 78306) supplemented by plain x-rays (see: **Nuclear Medicine (NM) Imaging in Oncology [ONC-1.3]** for additional bone scan codes)
ANY of the following: • Bone scan is not feasible or readily available • Bone scan is equivocal or indeterminate • Continued suspicion despite negative/inconclusive bone scan or other imaging modalities • Soft tissue component suspected on other imaging modalities • Differentiate neoplastic disease from Paget's disease of the bone	EITHER of the following: • MRI without and with contrast of the involved body site • CT without or with contrast of the involved body site

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Indication	Medically Necessary Imaging Study
Bone metastases suspected and **both** bone scan and either CT or MRI are inconclusive	• ^{18}F-FDG-PET/CT (CPT® 78815 or CPT® 78816)
EITHER of the following: • No prior cancer history with suspected bone metastatic disease or pathologic fracture on plain x-ray • Adult individuals with a biopsy-proven carcinoma of unknown origin in a bone lesion	• See: **Carcinoma of Unknown Primary Site (ONC-31.7)**

Evidence Discussion

Bone scan supplemented by plain x-ray is the generally the first-line modality for individuals with current or history of malignancy who have new bone pain, rising tumor markers or elevated alkaline phosphatase. Bone scan is 79%-86% sensitive and 81%-88% specific for metastatic lesions.[41,44] Bone scan allows rapid whole-skeletal evaluation, to ensure additional bony disease is not missed by focusing on a single site of cross-sectional imaging. MRI is a useful problem-solving tool if there is continued suspicion for bony metastatic disease with a negative bone scan.[41,43] MRI is supported when a soft tissue component is suspect to avoid understaging and undertreatment.[43] MRI is also the most specific study to supplement plain x-ray to differentiate Paget disease of bone from neoplastic disease.[45]

MRI is more accurate than CT or bone scan for the evaluation of malignant vertebral compression fractures and additionally can assess for cord compression, edema or leptomeningeal disease.[44] Individuals with known stage IV cancer with new back pain or any sings of neurologic compromise may be immediately evaluated by MRI of the whole spine without or without and with contrast.[44] MRI is also indicated for suspected leptomeningeal disease.[44] CT has the lower accuracy than MRI or bone scan in this setting and is only supported when MRI is contraindicated.[44] New leptomeningeal disease should prompt an MRI of the brain for complete neuroaxis imaging.

Where imaging is suspicious for bony metastatic disease and a workup for multiple myeloma is negative, CT Chest, Abdomen, and Pelvis with contrast are supported to look for a primary malignancy.[33]

The sensitivity and specificity of FDG PET-CT for bony metastatic disease varies with the malignancy. For example, for breast cancer, PET may be more sensitive (96% vs 76% for bone scan) but may be less specific (92% vs 95% for bone scan). However,

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for some cancers sensitivity of PET is as low as 56%.[42,44] Given this variability, PET/CT is supported as a problem-solving tool when both bone scan and MRI or CT are inconclusive. NCCN does support the use of FDG PET/CT specifically in individuals who 40 years of age or older and who have a symptomatic bone lesion with an abnormal x-ray.[63] These guidelines allow the flexibility of using FDG PET/CT in this specific scenario if it is desired in lieu of diagnostic CT and bone scan. NaF PET is considered investigational due to varying sensitivity and specificity.[46,47]

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Spinal/Vertebral Metastases (ONC-31.6)

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- Individuals with stage IV cancer with new onset back pain can forgo a bone scan (and plain films) in lieu of an MRI with and without contrast of the spine.

Indication	Medically Necessary Imaging Study
Known cancer history and spinal cord compression suspected based on signs/ symptoms of neurological compromise, including, but not limited to: • Unexpected, sudden loss of bowel or bladder control • Sudden loss of ability to ambulate • Complete loss of pinprick sensation corresponding to a specific vertebral level • Loss of pain at a site that had previously been refractory to pain management	MRI Cervical (CPT® 72156), MRI Thoracic (CPT® 72157), and MRI Lumbar Spine (CPT® 72158) without and with contrast OR without contrast • CT Cervical (CPT® 72126), CT Thoracic (CPT® 72129), and CT Lumbar (CPT® 72132) Spine if MRI is contraindicated
Individual with a known history of cancer and ANY of the following: • Metastatic or stage IV cancer with new or worsening back pain • Continued suspicion despite negative/ inconclusive bone scan or other imaging modalities • Back pain and suspicion of spinal malignancy based on any one of the following: ◦ Night pain ◦ Age >70 years ◦ Uncontrolled or unintentional weight loss ◦ Pain unrelieved by change in position ◦ Severe or worsening spinal pain	ONE of the following: • MRI of the relevant spinal level without contrast • MRI of the relevant spinal level without and with contrast • CT of the relevant spinal level without contrast • CT Myelogram of the relevant spinal level

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Indication	Medically Necessary Imaging Study
Monitoring untreated vertebral metastases	One of the following, every 3 months for 1 year: • MRI without and with contrast of the involved spinal level • CT without or with contrast of the involved spinal level **Imaging beyond 1 year is based on any new clinical signs/symptoms
Monitoring metastases within the spine treated with surgery and/or radiation therapy	One of the following, once within 3 months post-treatment, and then every 3 months for 1 year: • MRI without and with contrast of the involved spinal level • CT without or with contrast of the involved spinal level **Imaging beyond 1 year is based on any new clinical signs/symptoms

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Indication	Medically Necessary Imaging Study
Leptomeningeal involvement with cancer	Suspected: • MRI Brain without and with contrast (CPT® 70553) and MRI Cervical (CPT® 72156), Thoracic (CPT® 72157), and Lumbar spine (CPT® 72158) without and with contrast • CT Cervical (CPT® 72127), Thoracic (CPT® 72130), and Lumbar Spine (CPT® 72133) without and with contrast can be approved if MRI is contraindicated or not readily available On active treatment: • MRI Brain without and with contrast (CPT® 70553) and MRI Cervical (CPT® 72156), Thoracic (CPT® 72157), and Lumbar spine (CPT® 72158) without and with contrast every 2 cycles • CT without or with contrast of the involved spinal level if MRI is contraindicated Once treatment completed: • Routine advanced imaging not medically necessary for surveillance in asymptomatic individuals

Evidence Discussion

The incidence of malignant cord compression varies with cancer type but is rarely the first sign of systemic cancer. Back pain is the most common presenting symptoms and is reported in 80%-95% of individuals. Pain is often refractory to traditional pain medications. Sensory and motor deficits occur in 35%-75% of individuals, and acute bowel/bladder dysfunction are other red flags for cord compression. Up to 35% of individuals have multiple levels of compression, which may be non-contiguous, and as such where symptoms as above suggest cord compression in an individual with a history of malignancy, imaging of the whole spine is warranted. MRI with and without contrast has a sensitivity and specificity of 93% and 97%, respectively. ACR Appropriateness Criteria® stated CT Myelogram 'may be appropriate' in this setting, may be faster to obtain, and may be necessary to plan surgical intervention; thus, it is also supported by these guidelines for suspected malignant cord compression.[24,25,26]

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Some individuals will present with more localized symptoms suggestive of localized nerve root involvement but not consistent with the above symptoms of cord compression. Unilateral symptoms suggest a lower motor neuron lesion. Other symptoms suggestive of nerve root involvement are night pain, refractory pain, and pain unrelieved by a change in position. Elderly individuals with a cancer history are also at higher risk for nerve root involvement. Unintentional weight loss without other localizing symptoms may also suggest nerve root involvement. In individuals with a history of malignancy with any of the above, MRI without and with contrast of the involved spinal level of symptoms is supported. CT is less sensitive than MRI in this setting and is supported only when MRI is contraindicated.[24,25,26]

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Carcinoma of Unknown Primary Site (ONC-31.7)

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General Considerations

- Defined as carcinoma found in a lymph node or in an organ known not to be the primary for that cell type (e.g., adenocarcinoma arising in the brain or in a neck lymph node).
- This guideline also applies to a pathologic fracture that is clearly due to metastatic neoplastic disease in an individual without a previous cancer history.
- Detailed history and physical examination including pelvic and rectal exams and laboratory tests to be performed before advanced imaging.
- Individuals presenting with a thoracic squamous cell carcinoma described as metastatic appearing on chest imaging, or in lymph nodes above the clavicle, should undergo a detailed head and neck examination by a clinician skilled in laryngeal and pharyngeal examinations, especially in smokers.
- Individuals with suspected unknown primary based on only suspicious lytic bone lesions should be considered for serum protein electrophoresis (SPEP); urine protein electrophoresis (UPEP) and serum free light chains prior to consideration of extensive imaging.

Indication	Medically Necessary Imaging Study
Carcinoma found in a lymph node or in an organ known not to be primary	• CT Chest (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Neck with contrast (CPT® 70491) if cervical or supraclavicular involvement • CT with contrast or MRI without and with contrast of any other symptomatic site • For female individuals: ◦ Diagnostic (not screening) mammogram and full pelvic exam ◦ MRI Breasts Bilateral (CPT® 77049) if pathology consistent with breast primary and mammogram is inconclusive

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Indication	Medically Necessary Imaging Study
Sebaceous carcinoma of the skin (can be associated with underlying primary malignancy)	• CT Chest (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177) • CT Neck with contrast (CPT® 70491) if cervical or supraclavicular involvement • CT with contrast or MRI without and with contrast of any other symptomatic site
Axillary adenocarcinoma	• Diagnostic (not screening) mammogram and full pelvic exam • MRI Breasts Bilateral (CPT® 77049) if pathology consistent with breast primary and mammogram is inconclusive • If the above are non-diagnostic for primary site: ◦ CT Neck (CPT® 70491), CT Chest (CPT® 71260), and CT Abdomen (CPT® 74160) with contrast ◦ CT with contrast or MRI without and with contrast of any other symptomatic site
EITHER of the following: • Carcinoma found within a bone lesion • Unexplained pathologic fracture	• CT Chest (CPT® 71260) and CT Abdomen and Pelvis with contrast (CPT® 74177) • Bone Scan (CPT® 78306) (see: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes) • CT with contrast or MRI without and with contrast of any symptomatic site
ANY of the following: • Above studies have failed to demonstrate site of primary • CT scans reveal isolated metastatic disease for which definitive curative therapy is planned	• PET/CT (CPT® 78815 or CPT® 78816)
Post-treatment surveillance	• No advanced imaging for routine surveillance of asymptomatic individuals after treatment completion

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Evidence Discussion

Carcinoma of unknown primary site (CUP) is defined as carcinoma found in a lymph node or in an organ known not to be the primary for that cell type (e.g., adenocarcinoma arising in the brain or in a neck lymph node). This guideline also applies to a pathologic fracture that is clearly due to metastatic neoplastic disease in an individual without a previous cancer history. Individuals with suspected unknown primary based on only suspicious lytic bone lesions should be considered for serum protein electrophoresis (SPEP); urine protein electrophoresis (UPEP) and serum free light chains prior to consideration of extensive imaging.

CUP generally occurs in older adults, the majority 6-75 years, and accounts for 2-9% of all tumors. Median survival is poor, at 3-10 months. Twenty percent of individuals fall into a more favorable risk group with median survival >1 year, and imaging may help identify this group.[1,30] The primary step in workup of CUP, before advanced imaging, is a detailed history and physical examination including pelvic and rectal exams and laboratory tests, including basic CBC/Chemistries/LFTs but also tumor markers, immunohistochemistry, and PSA (for men over 40). Endoscopy should also be considered if pathology suggests a GI primary. CT of the chest, abdomen, and pelvis with contrast is supported for all individuals where primary site is not suggested on physical and lab evaluation, in alignment with NCCN and the European Society of Medical Oncology (ESMO).[1,30] CT Neck may be included if cervical or supraclavicular involvement, as well as CT or MRI for other symptomatic sites or abnormal sites on physical, with the choice of modality driven by body site of interest. If the site of carcinoma is a bone lesion that is not consistent with multiple myeloma, a bone scan should be added to the workup. Morphology on bone scan can help determine the primary site, where lytic lesions are most suggestive of myeloma, renal cell, GI and melanoma, and blastic lesions most commonly occur with prostate cancer and GI carcinoid. Other morphologic features such as location and expansile nature can also help guide workup and treatment toward a particular primary site.[33] PET/CT has not been shown to be superior to bone scan for this purpose, and in fact may be less sensitive than bone scan for lesions <1cm.[1,33]

It is essential that female individuals have a diagnostic (not screening) mammogram and full pelvic exam. If pathology is consistent with breast cancer from axillary node or other metastatic site, but mammogram is inconclusive, a bilateral breast MRI with and without contrast is supported, as MRI may identify the breast as the primary site in approximately half of the individuals presenting with axillary adenocarcinoma metastases.[1,32] If a primary site is still not found, CT Neck, Chest, Abdomen, and Pelvis are supported.

These guidelines align with NCCN and support PET/CT as a problem-solving tool to look for a primary site of disease when the studies described above still do not reveal a primary site.[1] PET is of intermediate specificity in this setting and large randomized trials

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are lacking.[1] A meta-analysis on the use of PET/CT in individuals with CUP found that primary tumors were detected in 37% of 433 individuals across 11 studies, with pooled sensitivity and specificity of 84%.[1,31] In addition, if CT scans reveal oligometastatic disease and definitive curative therapy is planned, the absence of other sites of disease may be confirmed with PET/CT to prevent over- or under-treatment.[1,30]

Subsequent imaging and surveillance should follow the guideline for each primary site, once a likely primary has been established. NCCN stated follow-up should be with history and physical with subsequent diagnostic testing based on symptoms. In 20%-50% of individuals, the primary site remains unidentified even after postmortem examination, thus continued imaging is low-yield and may contribute to the significant distress associated with the uncertainty of this condition.[1,30] There is no data-driven algorithm for imaging surveillance when the primary site of disease remains undiscovered.[1]

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Extrathoracic Small Cell and Large Cell Neuroendocrine Tumors (ONC-31.8)

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- All poorly-differentiated or high-grade, small cell and large cell neuroendocrine tumors arising outside the lungs or of unknown primary origin are imaged according to these guidelines.
- For intrathoracic poorly differentiated neuroendocrine cancer, see: **Small Cell Lung Cancer (ONC-7)**

Indication	Medically Necessary Imaging Study
Initial staging	ONE of the following combinations: • CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast • CT Chest with contrast (CPT® 71260) and MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)
Inconclusive findings on conventional imaging studies	• PET/CT (CPT® 78815)
ANY of the following: • Poorly differentiated neuroendocrine cancers of the head or neck • Signs or symptoms of CNS involvement	• MRI Brain without and with contrast (CPT® 70553)
Restaging during treatment	ONE of the following combinations, every 2 cycles: • CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) and CT of any known sites of disease with contrast • CT Chest with contrast (CPT® 71260) and MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197) and CT with contrast of any known sites of disease

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Indication	Medically Necessary Imaging Study
Suspected Recurrence	ANY or ALL of the following are medically necessary: • CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast or CT Chest with contrast (CPT® 71260) and MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197) • MRI Brain without and with contrast (CPT® 70553) • Bone scan (CPT® 78306) (See: **Nuclear Medicine (NM) Imaging in Oncology (ONC-1.3)** for additional bone scan codes) • PET imaging is generally **not** medically necessary but can be considered for rare circumstances.
Surveillance	ONE of the following combinations every 3 months for 1 year, then every 6 months: • CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) • CT Chest with contrast (CPT® 71260) and MRI Abdomen without and with contrast (CPT® 74183) and MRI Pelvis without and with contrast (CPT® 72197)

Evidence Discussion

Poorly differentiated/high-grade neuroendocrine tumors (NET) may occur anywhere in the body and exhibit more aggressive behavior than other neuroendocrine tumors. When these tumors occur in the lung, they are managed like small cell lung cancer and the small-cell lung cancer guidelines apply. This section refers to extrathoracic, poorly-differentiated or high-grade NETs.

Initial Staging

Initial staging with contrasted CT of the chest, abdomen and pelvis is supported, with sensitivity and specificity ranging from 82%-100% .[9,51] Metastatic disease, particularly to the liver, is common with this entity within this setting .[48,49] MRI is equally supported by NCCN for imaging of the abdomen and pelvis. Given the undifferentiated nature of these tumors, dotatate PET/CT is not routinely supported as they do not consistently have somatostatin receptors, with some studies showing this modality missing 50% of tumors.[49] Sensitivity and specificity of FDG PET/CT is superior to somatostatin-receptor based imaging for undifferentiated tumors, but is still widely variable and is not supported for first line imaging but may be used as a problem-solving tool when conventional imaging is inconclusive.[9,50] Poorly differentiated NETs do have a

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propensity for CNS involvement, and MRI brain with and without contrast is supported for initial staging with head and neck primary site or for any signs and symptoms suggestive of CNS involvement .[9,49] Suspected bony metastatic disease may be evaluated using guideline **ONC-31.5**.

Restaging and suspected recurrence

In alignment with NCCN, conventional imaging may be repeated every 2 cycles of treatment. In the case of suspected recurrence, CT Chest, Abdomen, and Pelvis with contrast are supported as well and MRI brain and Bone scan, in alignment with NCCN .[9] FDG PET/CT is not routinely supported in this setting for the reasons cited in the section on initial staging but may be utilized in rare circumstances in the interest of safety.

Surveillance

Guidelines support conventional imaging studies every 3 months for the first year, then every 6 months for 4 additional years, then annually indefinitely due to the long term-risk of recurrence in this entity.[9,48]

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Primary Peritoneal Mesothelioma (ONC-31.9)

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Indication	Medically Necessary Imaging Study
Initial staging	• CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast • PET/CT (CPT® 78815) if there is no evidence of metastatic disease or conventional imaging is inconclusive
Recurrence/ Restaging	• If there is known prior disease, CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast • PET for inconclusive finding on conventional imaging
Surveillance	• CT Abdomen and Pelvis with contrast (CPT® 74177) every 3-6 months for 5 years, then annually until year 10

Evidence Discussion

Contrasted CT of chest, abdomen and pelvis is essential to assess the degree of dissemination, verify that peritoneal disease is not metastatic from another primary site, evaluate lymphadenopathy, and to identify metastatic disease. For primary peritoneal mesothelioma, most individuals present with advanced locoregional disease.[35] Spread into pleural space and local lymph nodes are the primary sites of metastatic disease, with more distant/diffuse metastatic disease much less common.[35,36] Sensitivity of CT is superior to MRI for this entity. As with other malignancies, if CT shows a liver lesion indeterminate for metastatic disease, MRI may be used for further assessment per guideline section ONC-31.2. The sensitivity of PET-CT for malignant peritoneal mesothelioma ranges from 58%-100%, so it is not a primary imaging tool for staging. However, PET/CT may detect small peritoneal implants that are missed on CT and alter management.[34] These guidelines support PET/CT when no metastatic disease is detected on conventional imaging to ensure individuals are not under-staged.

Contrasted CT of the abdomen and pelvis are supported for restaging, as sensitivity of CT is superior to MRI for this disease process. Given that progression to chest disease is rare, CT Chest is supported for restaging only if there is known disease in the chest or if new chest symptoms develop. Given the widely variable sensitivity of PET/CT for peritoneal mesothelioma, it is supported only for inconclusive findings on conventional imaging.[35]

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NCCN guidelines and outcome data supported contrasted CT of the Chest/Abdomen/ Pelvis every 3 months for 2 years then annually until year 10.[34,35] Frequent imaging is supported only within the first two years as 68% of recurrences occur within the first 2 years, then annual imaging moving forward.[35]

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Kaposi's Sarcoma (ONC-31.10)

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Indication	Medically Necessary Imaging Study
Kaposi's Sarcoma	• Advanced imaging is not medically necessary since disease is generally localized to skin. • CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast at initial diagnosis. If initial scans are negative then future imaging would be based on signs or symptoms.

Evidence Discussion

Most Kaposi Sarcoma (KS) is most often confined to skin; however, it can sometimes be found in viscera, particularly in HIV-associated disease. To prevent under-staging and to assess the need for systemic therapy, CT of the Chest, Abdomen, and Pelvis with contrast are supported at initial diagnosis.[61]

Routine advanced imaging is not supported if there is no visceral disease at diagnosis, but restaging CTs may be approved for individuals with visceral disease on systemic therapy per the timeframes offered in ONC-1.2. Contrasted CTs may also be approved to evaluate areas with specific signs and symptoms of new involvement.[61]

There are no data or expert consensus that support routine surveillance imaging for Kaposi's Sarcoma.[61]

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Castleman's Disease (Unicentric and Multicentric) (ONC-31.11)

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Indication	Medically Necessary Imaging Study
Initial staging	• Either CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast **or** PET/CT (CPT® 78815) • CT Neck with contrast (CPT® 70491) if cervical or supraclavicular involvement • If CT scans were utilized initially and suggested unicentric disease, and surgical resection is being considered, PET/CT (CPT® 78815) can be approved to confirm unicentric disease • If unicentric disease is surgically removed, proceed to surveillance section
Restaging: • Multicentric disease or surgically unresected unicentric disease on chemotherapy	ONE of the following every 2 cycles: • CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast • PET/CT (CPT® 78815)
ANY of the following: • Suspected recurrence • Recurrent B symptoms • Rising LDH/IL-6/ VEGF levels	ONE of the following: • CT Chest (CPT® 71260) and CT Abdomen and Pelvis (CPT® 74177) with contrast • PET/CT (CPT® 78815)
Surveillance	• CT with contrast of involved areas no more than every 6 months up to 5 years

Evidence Discussion

Initial Staging

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PET/CT fusion is supported for initial staging of Castleman's Disease.[37] PET/CT not only assesses for multicentric disease, but the SUV can be used to determine Castleman's disease vs frank lymphoma.[39] Diagnostic, contrasted CTs of the chest, abdomen, pelvis, as well as neck (if suspected neck disease) may be substituted for PET/CT, but diagnostic CT is not generally supported concurrently with PET.[37] However, if diagnostic CTs were utilized initially and surgical resection is being considered, these guidelines allow a PET/CT to be done subsequently in the interest of safety, to confirm unicentric disease and prevent under-staging.

Restaging/Recurrence

Unicentric disease that is surgically resected is considered to be in surveillance and imaging follows surveillance guidelines. For multicentric disease (MCD) or unresected unicentric disease on chemotherapy, disease may be monitored every 2 cycles with contrasted CT of the chest, abdomen and pelvis or PET/CT fusion studies, in alignment with NCCN. The same imaging is supported for suspected recurrence or labs concerning for development of POEMS-associated MCD or HHV-8 MCD, as these entities are rapidly aggressive[38,39] Concurrent contrasted diagnostic CTs with PET/CT fusion studies do not generally change management and as such are not supported, nor are concurrent scans suggested by NCCN or international consensus recommendations.[37-40]

Surveillance

There are no clear consensus guidelines for imaging surveillance of Castleman's Disease. In the interest of safety, given a multitude of curative treatment options for recurrent disease, these guidelines support surveillance imaging with CT with contrast of involved body areas no more than every 6 months up to 5 years. PET/CT is not supported for surveillance in alignment with ASCO Choosing Wisely campaign.

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v1.0.2026

Instructions for Use

This Medical Policy provides assistance in interpreting United HealthCare Services, Inc. standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]) or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC) or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC) or contractual requirements for benefit plan coverage govern.

Before using this policy, please check the federal, state (OAC) or contractual requirements for benefit plan coverage. United HealthCare Services, Inc. reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

United HealthCare Services, Inc. uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, United HealthCare Services, Inc. may also use United HealthCare Services, Inc.'s Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Ohio Department for Medicaid Services. The United HealthCare Services, Inc.'s Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Policy History/Revision Information

Date	Summary of Changes
02/01/2024	Annual evidence-based updates
07/01/2024	Interim evidence-based updates
05/01/2025	Annual evidence-based updates
11/06/2025	Annual evidence-based updates

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