UnitedHealthcare® Community Plan: *Radiology Imaging Coverage Determination Guideline*

Breast Imaging Guidelines (For Ohio Only)

V1.0.2024

Guideline Number: CSRAD002OH.B

Effective Date: February 1, 2024

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 are coverage, age, timeframe, or quantity limits will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

The determination for breast imaging is made on a case-by-case basis with consideration of the individual's personal and family health history, physical examination findings, and symptoms (presenting or changes).

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Application (For Ohio Only)

Guideline Development (Preface-1)

Guideline

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- The UnitedHealthcare's 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. United HealthCare's 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.
- UnitedHealthcare supports the Choosing Wisely initiative **(https://www.choosingwisely.org/)** by the American Board of Internal Medicine (ABIM) Foundation and many national physician organizations, to reduce the overuse of diagnostic tests that are low value, no value, or whose risks are greater than the benefits.

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

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

References (Preface-2)

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 will be considered to determine whether they meet UnitedHealthcare's 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.

Legislative Mandate

- State and federal legislations may need to be considered in the review of advanced imaging requests.

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.

Clinical Information (Preface-3)

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Clinical Information (Preface-3.1)

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Clinical Documentation and Age Considerations

- UnitedHealthcare's 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. UnitedHealthcare's 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 should include a recent detailed history, physical examination[20] since the onset or change in symptoms, and/or laboratory and 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; x-ray imaging does not have to be within the past 60 days.
      - 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.
  - UnitedHealthcare's 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 age, comorbidities, and differences in disease natural history between children and adults.
  - Individuals who are 18 years old or younger[19] 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.
- The terms “male” and “female” used in these guidelines refer to anatomic-specific diseases and disease predispositions associated with the individual’s sex assigned at birth rather than their gender identity. It should be noted that gender identity and anatomic-specific diseases as well as disease predispositions are not always linked. As such, these guidelines should be applied to the individual’s corresponding known or suspected anatomic-specific disease or disease predisposition. At UnitedHealthcare, we believe that it is important to understand how all individuals, including those who are gender-diverse, choose to identify themselves. To ensure that gender-diverse individuals are treated with respect and that decisions impacting their healthcare are made correctly and with sensitivity, UnitedHealthcare recognizes all individuals with the following gender marker options: Male, Female, Transgender Male, Transgender Female, “X”, and “Not Specified.”

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.[1]

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
  - 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.
- 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.[1]
- 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 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.[2]
- Both contrast CT and MRI may be 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 may be appropriate if clinical criteria for CT with contrast are met AND the individual has:
  - 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
  - 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.
- MRI utilizing Xenon Xe 129 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 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 may be considered to have the same risk profile with renal failure (GFR <30 mL/min).[2]
  - 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.[3,4,5,6,7] 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.[8]
- A CT may be approved 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:
  - Caution should be taken in the use of gadolinium in individuals with renal failure.
  - The use of gadolinium contrast agents is 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 indicated 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.

Overutilization of Advanced Imaging

- A number of recent 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 indicated examination has been ordered for individuals, it may be possible to avoid exposing them to unnecessary risks.[9,10] 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 indicated if the surgery/procedure is not indicated. Once the procedure has been approved or if the procedure does not require prior authorization, the appropriate pre-procedural imaging may be approved.

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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, Mammogram, MRI Breast, US Breast, CT Colonography (virtual colonoscopy), Cardiac MRI, Cardiac CT, or Coronary CTA studies.
- 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.

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

PRF.CD.0004.2.A
v1.0.2024

- 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

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.[3]
- 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.
  - **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.

Unlisted Procedures/Therapy Treatment Planning (Preface-4.3)

PRF.CD.0004.3.UOH

v1.0.2024

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

- 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) can be considered in the following clinical scenarios:
  - Studies done for navigation and planning for neurosurgical procedures (i.e., Stealth or Brain Lab Imaging)[1,2]
  - 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 (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.

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

PRF.CD.0004.5.UOH

v1.0.2024

- 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 indicated 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.

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.

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

PRF.CD.0004.7.UOH
v1.0.2024

- 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.[4]
  - CPT® 76140 is the appropriate code to use for an exam which was completed elsewhere and a secondary interpretation of the images is requested.[5]

Quantitative MR Analysis of Tissue Composition (Preface-4.8)

PRF.CD.0004.8.A
v1.0.2024

- 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. At present, these procedures are primarily being used in clinical trials and there is no widely recommended indications in clinical practice. As such, these procedures are considered to be investigational and experimental for coverage purposes.
  - CPT® 0648T (without diagnostic MRI) and CPT® 0649T (with diagnostic MRI) refer to data analysis with and without associate imaging of a single organ, with its most common use being LiverMultiScan (LMS).
    - See **Fatty Liver (AB-29.2)** in the Abdomen Imaging Guidelines.
  - CPT® 0697T (without diagnostic MRI) and CPT® 0698T (with diagnostic MRI) refer to data analysis with and without associate imaging of a multiple organs, with its most common use being CoverScan.

HCPCS Codes (Preface-4.9)

PRF.CD.0004.9.UOH
v1.0.2024

- 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.[6]
  - 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.

References (Preface-4)

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Whole-Body Imaging (Preface-5)

Guideline

Whole-Body CT Imaging (Preface-5.1)

PRF.WB.0005.1.UOH
v1.0.2024

- Whole-body CT or LifeScan (CT Brain, Chest, Abdomen, and Pelvis) for screening of asymptomatic individuals is not indicated. 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 CT is supported for oncologic staging in Multiple Myeloma. See **Multiple Myeloma and Plasmacytomas (ONC-25)** in the Oncology Imaging Guidelines.

Whole-Body MR Imaging (Preface-5.2)

PRF.WB.0005.2.A
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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)**, **Hereditary Paraganglioma- Pheochromocytoma (HPP) Syndromes (PEDONC-2.13)**, or **Constitutional Mismatch Repair Deficiency (CMMRD or Turcot Syndrome) (PEDONC-2.15)** in the Pediatric Oncology Imaging Guidelines.
  - Cancer staging and restaging:
    - While the feasibility of WBMRI has been established, data remain conflicting on whether WBMRI is of equivalent diagnostic accuracy compared with standard imaging modalities such as CT, scintigraphy, and PET imaging.
    - Evidence has not been published establishing WBMRI as a standard evaluation for any type of cancer.
  - Autoimmune disease:
    - WBMRI can be approved in some situations for individuals with chronic recurrent multifocal osteomyelitis.
      - For additional information, see **Chronic Recurrent Multifocal Osteomyelitis (PEDMS-10.2)** in the Pediatric Musculoskeletal Imaging Guidelines.

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 may be appropriate in select circumstances when the following criteria are met:
  - 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.
- For more information, see **PET Imaging in Pediatric Oncology (PEDONC-1.4)** in the Pediatric Oncology Imaging Guidelines, and **PET Brain Imaging (PEDHD-2.3)** and **Special Imaging Studies in Evaluation for Epilepsy Surgery (PEDHD-6.3)** in the Pediatric Head Imaging Guidelines.

References (Preface-5)

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References (Preface-6)

Guideline

References (Preface-6.1)

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.
- The website addresses for certain references are included in the body of the guidelines but are not hyperlinked to the actual website.
- The website address for the American College of Radiology (ACR) Appropriateness Criteria® is **http://www.acr.org**.

Copyright Information (Preface-7)

Guideline

Copyright Information (Preface-7.1)

Copyright Information (Preface-7.1)

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Trademarks (Preface-8)

Guideline

Trademarks (Preface-8.1)

Trademarks (Preface-8.1)

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Breast Imaging Guidelines

Guideline

General Considerations (BR-Preface 1)

Guideline

Abbreviations for Breast Guidelines

General Guidelines (BR-Preface 1.0)

BI-RADS™ Categories Chart (BR-Preface 1.1)

BI-RADS™ Breast Density Categories (BR-Preface 1.2)

Abbreviations for Breast Guidelines

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Abbreviations for Breast Guidelines	
BI-RADS™	Breast Imaging Reporting and Database System
BRCA	tumor suppressor gene
CAD	computer-aided detection
CT	computed tomography
CTA	computed tomography angiography
CTV	computed tomography venography
DCIS	ductal carcinoma in situ
FDA	Food and Drug Administration
FDG	fluorodeoxyglucose
FNA	fine needle aspiration
HRCT	high resolution computed tomography
LCIS	lobular carcinoma in situ
MRA	magnetic resonance angiography
MRI	magnetic resonance imaging
PEM	positron-emission mammography
PET	positron emission tomography

General Guidelines (BR-Preface 1.0)

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- A current clinical evaluation since the onset or change in symptoms is usually required prior to considering advanced imaging.
  - A clinical evaluation should include the following:
    - A relevant history and physical examination since the onset or change in symptoms
    - Appropriate laboratory studies and non-advanced imaging modalities, such as mammogram and/or ultrasound
    - Other meaningful contact (telephone call, electronic mail or messaging)

    since the onset or change in symptoms by an established individual can substitute for a face-to-face clinical evaluation.
- Current clinical evaluation is not required prior to screening studies.
- Throughout this guideline, when MRI Breast is indicated any **ONE** of the following codes is supported:
  - CPT® 77049 MRI Breast Bilateral, including CAD, with and without contrast
  - HCPCS C8908 MRI Breast Bilateral, with and without contrast
- If the individual has breast implants, the following code is supported when MRI Breast is requested to assess integrity of breast implants **AND** is also indicated in the guidelines:
  - CPT® 77047 MRI Breast Bilateral, without contrast

BI-RADS™ Categories Chart (BR-Preface 1.1)

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BI-RADS™ Categories Chart	
Category	**Description**
Category 0: Incomplete	Need additional imaging evaluation or prior mammograms for comparison. Category 0 classification requires that additional imaging study be specified, e.g., ultrasound, additional mammogram view, MRI.
Category 1: Negative	There is nothing to comment on. The breasts are symmetrical and no masses, architectural disturbances, or suspicious calcifications are present.
Category 2: Benign Finding	This is also a negative mammogram, but the interpreter may wish to describe a finding. Involuting, calcified fibroadenomas, multiple secretory calcifications, fat-containing lesions (such as oil cysts, lipomas, galactoceles, and mixed density hamartomas) all have characteristic appearances, and may be labeled with confidence. The interpreter might wish to describe intramammary lymph nodes, implants, etc. while still concluding that there is no mammographic evidence of malignancy.
Category 3: Probably Benign Finding – Short Interval Follow-up Suggested	A finding placed in this category should have a very high probability of being benign. It is not expected to change over the follow-up interval, but the radiologist would prefer to establish its stability. Data is becoming available that sheds light on the efficacy of short interval follow-up. At the present time, most approaches are intuitive. These will likely undergo future modification as more data accrue as to the validity of an approach, the interval required, and the type of findings that should be followed.

BI-RADS™ Categories Chart	
Category	**Description**
Category 4: Suspicious Abnormality – Biopsy Should Be Considered	There are lesions that do not have the characteristic morphologies of breast cancer but have a definite probability of being malignant. The radiologist has sufficient concern to urge a biopsy. If possible, the relevant possibilities should be cited so that the individual and her physician can make the decision on the ultimate course of action.
Category 5: Highly Suggestive of Malignancy – Appropriate Action Should Be Taken	These lesions have a high probability of being cancer and should be biopsied or treated surgically.
Category 6: Known Biopsy-Proven Malignancy – Appropriate Action Should Be Taken	These lesions have been biopsied and are known to be malignant.

BI-RADS™ Breast Density Categories (BR-Preface 1.2)

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BI-RADS™ Breast Density Categories
Category A: Almost entire fatty
Category B: Scattered fibroglandular densities
Category C: Heterogeneously dense
Category D: Extremely dense

Breast Ultrasound (BR-1)

Guideline

Breast Ultrasound (BR-1.1)

- Routine performance of breast ultrasound as stand-alone screening or with screening mammography is not indicated.
  - Breast ultrasound is a supplemental screening alternative for high-risk females (as described in **MRI Breast Indications [BR-5]**) with dense breasts on mammography, when MRI Breast without and with contrast cannot be performed. The inability to perform MRI Breast may be because it cannot be tolerated (i.e., insurmountable claustrophobia or body habitus), or there exists a contraindication (i.e., non-MRI compatible implantable devices or an inability to receive MRI contrast). When a MRI Breast has not been performed in the past year for high-risk screening, then a bilateral breast ultrasound requested for supplemental screening in high-risk females with dense breasts on mammography is supported.
  - Equivocal or Occult Findings:
    - Breast ultrasound (CPT® 76641 or CPT® 76642): Radiologist Report recommendation and inconclusive or conflicting findings on mammography or MRI Breast
- Breast ultrasound (CPT® 76641: unilateral, complete; or, CPT® 76642: unilateral, limited) can be used to further evaluate abnormalities found on mammogram, especially in differentiating cysts from solid lesions.
  - A clinical office visit is not necessary prior to breast ultrasound when an abnormality has been identified on recent (within the last 60 days) mammogram.
- BI-RADS™ Cat 3 ultrasound follow-up imaging for stable findings at 6 months:
  - If repeat imaging remains BI-RADS™ 3, repeat at 12 months, 18 months, and 24 months from the date of the initial imaging.
    - After 2 years of stability, the finding should be assessed as benign (Cat 2).
  - If repeat imaging is BI-RADS™ 1 or 2, then imaging reverts to routine per individual's risk profile.
  - Mammography and breast ultrasound, in any order, regardless of age for palpable breast masses or other clinical abnormalities (such as skin change, pain, nipple inversion). Ultrasound can enhance biopsy.
- If recent clinical examination is equivocal for rupture of breast implants (saline or silicone), initial imaging is indicated as below:

Evaluation of Suspected Rupture of Breast Implants		
Age	**Saline Breast Implant**	**Silicone Breast Implant**
<30	Breast Ultrasound	Breast Ultrasound or MRI Breast without contrast (CPT® 77047)

Evaluation of Suspected Rupture of Breast Implants		
Age	**Saline Breast Implant**	**Silicone Breast Implant**
30-39	Breast Ultrasound or mammography/Digital breast tomosynthesis (DBT)	Breast Ultrasound, mammography/Digital breast tomosynthesis (DBT) or MRI Breast without contrast (CPT® 77047)
≥40	Mammography/Digital breast tomosynthesis (DBT)	Mammography/Digital breast tomosynthesis (DBT) or MRI Breast without contrast (CPT® 77047)

- Axilla ultrasound (CPT® 76882)
  - For females with clinically suspicious lymph nodes, pre-operative axillary ultrasound with a FNA or biopsy can help identify individuals who have positive nodes.
    - See **Axillary Lymphadenopathy (and Mass) (CH-2.2)** in the Chest Imaging Guidelines.
  - Bilateral should be coded CPT® 76882 x 2.
- US-guided breast biopsy (CPT® 19083) includes the imaging component.
  - Additional lesions should be billed using CPT® 19084.
- Ultrasound Breast can be repeated at least 6 months after an US-directed breast biopsy to document successful lesion sampling if histology is benign and non-specific, equivocal or uncertain.
- 3D Reconstruction (CPT® 76376 or CPT® 76377) is **NOT** indicated for breast ultrasound. It is commonly requested in conjunction with automated breast ultrasound (ABUS); there is no evidence to support its clinical usefulness.
- State-Specific Density Reporting and Imaging Mandate Laws
  - Breast density notification laws have been put into effect by many states. Breast density notification laws vary, but some also contain mandates for additional imaging, which may include MRI and/or ultrasound. For applicable requests involving members in these states, their legislative mandates should be followed.

MRI Breast Coding (BR-2)

Guideline

MRI Breast Coding (BR-2.1)

- The use of gadolinium contrast is required for the evaluation of breast parenchyma.
- The use of gadolinium contrast is **NOT** necessary for the evaluation of implant integrity in asymptomatic, average-risk individuals.
- Computer-aided detection (CAD) is included with the MRI Breast CPT® 77049 and CPT® 77048 procedures. The use of HCPCS code C8937 (CAD including computer algorithm analysis of MRI Breast data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation) is **NOT** necessary with these procedures.
  - The use of CAD has little influence on the sensitivity and specificity of MRI Breast interpretation.
  - The use of HCPCS code C8937 (CAD including computer algorithm analysis of MRI Breast data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation) is currently considered investigational, experimental, and/or unproven.
  - Since the CAD software automatically performs 3D imaging, CPT® 76376 or CPT® 76377 should **NOT** be used in conjunction with MRI Breast.
- MRI-guided breast biopsy (CPT® 19085) includes the imaging component and the needle placement under MR guidance; CPT® 77021 MR guidance for needle placement is **NOT** an indicated code to bill for a breast biopsy.
  - Additional lesions should be billed using CPT® 19086.

Background and Supporting Information

- Although MRI Breast has superior sensitivity in identifying new unknown malignancies, it carries a significant false positive risk when compared to mammogram and ultrasound. Incidental lesions are seen on 15% of MRI Breast and increase with younger age. The percentage of incidental lesions that turn out to be malignant varies from 3% to 20% depending on the individual population. Cancer is identified by MRI Breast in only 0.7% of those with “inconclusive mammographic lesions.”

Breast Reconstruction (BR-3)

Guideline

Breast Reconstruction (BR-3.1)

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- CTA or MRA of the body part from which the free-tissue transfer flap is being taken, can be performed for breast reconstruction pre-operative planning.
  - For example, CTA Abdomen and/or Pelvis (CPT® 74175 or CPT® 72191 or CPT® 74174) or MRA Abdomen and/or Pelvis (CPT® 74185 and/or CPT® 72198) for Deep Inferior Epigastric Perforators (DIEP) flap.
- Routine use of CTA Chest (CPT® 72175) to evaluate recipient vessels is **NOT** indicated.
  - **Criteria exception**: In circumstances where there has been previous cardiac/vascular surgery and/or known vascular anomalies in the chest, it may be warranted.
- There is currently insufficient evidence-based data to support the need for routine advanced imaging for TRAM flaps or other flaps performed on a vascular pedicle.

MRI Breast Indications (BR-5)

Guideline

MRI Breast Indications (BR-5.1)

MRI Breast Indications (BR-5.1)

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The determination for breast imaging is made on a case-by-case basis with consideration of the individual's personal and family health history, physical examination findings, and symptoms (presenting or changes).

Breast MRI Considerations

- When MRI Breast imaging is clinically indicated (per the criteria listed in the sections below), an MRI Breast Bilateral with and without contrast is supported.
- MRI Breast Unilateral is **NOT** clinically supported.
- See **Breast Ultrasound (BR-1)** when there is a contraindication to MRI contrast.
- See **MRI Breast Coding (BR-2)** for MRI-guided breast biopsy.
- See **Breast Cancer (ONC-11)** in the Oncology Imaging Guidelines for imaging indications related to breast cancer as follows:
  - Breast Cancer - Initial work-up/Staging
  - Breast Cancer - Restaging/Recurrence
  - Breast Cancer - Surveillance/Follow-up
  - Annual screening with prior history of breast cancer

Suspected Rupture of Breast Implants

- Routine surveillance imaging for asymptomatic individuals to assess the integrity of breast implants (silicone or saline) is **NOT** supported.
- Breast MRI is **NOT** indicated for evaluation of capsular contracture.
- For suspected rupture of breast implants (saline or silicone), with a recent equivocal clinical examination and/or conventional imaging, the imaging for further evaluation is indicated in the table below:

Evaluation of Suspected Rupture of Breast Implants		
Age	**Saline Breast Implant**	**Silicone Breast Implant**
<30	Breast Ultrasound	Breast Ultrasound or MRI Breast without contrast (CPT® 77047)
30-39	Breast Ultrasound or mammography/Digital breast tomosynthesis (DBT)	Breast Ultrasound, mammography/Digital breast tomosynthesis (DBT) or MRI Breast without contrast (CPT® 77047)
≥40	Mammography/Digital breast tomosynthesis (DBT)	Mammography/Digital breast tomosynthesis (DBT) or MRI Breast without contrast (CPT® 77047)

Malignant Phyllodes Tumor (Cystosarcoma Phyllodes)

- MRI Breast is indicated pre-operatively to establish extent of disease where a diagnosis of malignant phyllodes tumor has previously been established by tissue diagnosis. See **Background and Supporting Information**.

Mammogram and/or US with Equivocal or Occult Findings

- MRI Breast is **NOT** indicated to determine biopsy recommendations for suspicious or indeterminate lesion(s) that can be readily biopsied, either using imaging guidance or physical exam, such as palpable masses and microcalcifications.
- MRI Breast is indicated for **EITHER** of the following:
  - Radiologist Report Recommendation for MRI Breast to assess inconclusive or conflicting findings on mammography or ultrasound with **EITHER** of the following:
    - Findings that are not associated with a discrete palpable mass.
    - Inconclusive findings of fat necrosis (most commonly due to trauma or surgery) in an individual with a history of breast cancer treated with surgery (lumpectomy or mastectomy with or without reconstruction).
  - Documented histopathologic discordance between core-needle biopsy findings and imaging findings. MRI Breast is indicated for further evaluation **after** the discordant biopsy (before consideration for surgical management vs. observation).
    - Discordance exists w 62hen the biopsy result does not adequately explain the abnormal (BI-RADS™ 4 or 5) findings on mammogram and/or ultrasound.
- See **MRI BI-RADS™ 3** section for lesions categorized as BI-RADS™ 3 on MRI.
- Lesions that are categorized as BI-RADS™ 3 (low risk, probably benign) on **mammogram and/or ultrasound** are not considered equivocal. MRI Breast is **NOT** indicated for these lesions.
  - Repeat the original study type (mammogram or US) in 6 months
    - If repeat imaging remains BI-RADS™ 3, repeat original study type at 12 months, 18 months, and 24 months from the date of the initial imaging.
      - After 2 years of stability, the finding should be assessed as benign (Cat 2).
    - If repeat imaging is BI-RADS™ 1 or 2, then imaging reverts to routine per individual's risk profile. See **Risk Factors** section.
- MRI Breast is **NOT** indicated for suspicious (BI-RADS™ 4 or 5) lesion on mammogram and/or ultrasound.
  - A lesion categorized as BI-RADS™ 4 or 5 should be biopsied.

MRI BI-RADS™ 3

- A probably benign lesion on **MRI** (MRI BI-RADS™ 3) should undergo repeat MRI in 6 months.
  - If repeat imaging remains MRI BI-RADS™ 3, then repeat at 12 months, 18 months, and 24 months from the date of the initial imaging.
    - After 2 years of stability, the finding should be assessed as benign (Cat 2).
  - If repeat imaging is BI-RADS™ 1 or 2, then imaging reverts to routine per individual's risk profile. See **Risk Factors** section.
- For lesions initially seen on MRI Breast **and** that have benign and non-specific, equivocal or uncertain histology (based on stereotactic, MRI-guided or US-directed breast biopsy), an MRI Breast can be repeated at least 6 months after the biopsy to document successful lesion sampling.

Risk Factors

- To date, evidence does not suggest improved outcomes for individuals whose only risk factor is breast density. Therefore, MRI Breast is **NOT** indicated for individuals whose only risk factor is dense breasts as determined by mammogram.
  - See **Mammogram and/or US with Equivocal or Occult Findings** section.
- Routine MRI Breast following bilateral mastectomy is **NOT** indicated (even if high-risk screening criteria may otherwise be met).
- Annual MRI Breast screening is indicated for individuals meeting the high-risk criteria in the table below:

High-Risk Indications	
*MRI screening to begin at **age 20**:*	
1.	Li-Fraumeni Syndrome (TP53 mutation) should start annual breast screening MRI starting at age 20 **or** at the age of the earliest diagnosed breast cancer in the family, whichever comes first.
*MRI screening to begin at **diagnosis** but not prior to age 25:*	
2.	Individuals with a history of : • Atypical ductal hyperplasia (ADH) • Atypical lobular hyperplasia (ALH) • Lobular carcinoma in situ (LCIS)
*MRI screening to begin at **age determined by gene mutation**:*	
3.	BRCA 1 or BRCA 2 begin **age 25**
4.	STK11, Peutz-Jeghers syndrome (PJS), PTEN Mutation (Cowden Syndrome), CDH1, NF1, PALB2, ATM, CHEK2 begin **age 30**
5.	BARD1, RAD51C, RAD51D begin **age 40**
6.	The following have unknown or insufficient evidence of breast cancer risk and additional MRI screening is **NOT** indicated at this time: • MSH2, MLH1, MSH6, PMS2, EPCAM, NBN, genetic variants of unknown significance, genetic variants favoring polymorphism, and genetic variants of intermediate penetrance.

High-Risk Indications	
*MRI screening begins at **age 40**:*	
7.	If the individual has **NOT** been tested for BRCA mutation **and** there is a first-degree relative (parent, sibling, child; half-siblings are considered second-degree relatives) with BRCA 1 or BRCA 2 mutation • Annual screening is **NOT** indicated if the individual has been tested and is negative for BRCA 1 or BRCA 2 mutation unless they meet other criteria.
*MRI screening begins at **age 40** or **10 years before the age of relative** (lineage as described below) when **first diagnosed with breast cancer** but not prior to the age of 25*:	
8.	Two or more first-degree relatives with breast or ovarian cancer
9.	One first-degree relative with breast cancer or ovarian cancer that was diagnosed ≤ age 50
10.	One first-degree relative with bilateral breast cancer, or both breast and ovarian cancer
11.	A first- or second-degree male relative (father, brother/half-brother, uncle, grandfather) diagnosed with breast cancer
12.	Clinical lifetime-risk estimated at greater than or equal to 20% using an acceptable genetic-risk or clinical-risk estimator • Acceptable clinical-risk estimator models are Gail (NCI), Claus, Tyrer-Cuzick (IBIS), or BRCAPRO.
*MRI screening to begin at **age 25** or **8 years after completion of radiotherapy** (whichever occurs later - screening MRI Breast is not supported prior to age 25)*:	

High-Risk Indications	
13.	Annual MRI Breast and annual mammogram is recommended for individuals who received therapeutic radiation exposure in the following fields while they were under 30 years of age: • Chest (thorax) • Whole lung • Mediastinal • Axilla • Mini-mantle, mantle, or extended mantle • Total (TLI) or subtotal (SLTI) lymphoid irradiation • Total body irradiation (TBI)

Background and Supporting Information

- myRisk® Hereditary Cancer (Myriad Genetics, Inc.) is not accepted as a risk calculator to determine high-risk for breast cancer.
- MRI should not be used in lieu of biopsy of mammographically, clinically, and/or sonographically suspicious findings (ACR Practice Guidelines).
- State-Specific Density Reporting and Imaging Mandate Laws
  - Breast density notification laws have been put into effect by many states. Breast density notification laws vary, but some also contain mandates for additional imaging, which may include MRI and/or ultrasound. For applicable requests involving members in these states, their legislative mandates should be followed.
- Phyllodes Tumor (Cystosarcoma Phyllodes)
  - Phyllodes tumor is usually benign and has clinical characteristics of fibroadenoma, although they may exhibit rapid growth. MRI Breast has not been shown to be of value in distinguishing fibroadenoma from phyllodes tumor.
  - Diagnosis is made by tissue diagnosis (percutaneous core biopsy or excisional biopsy). FNA biopsy is inaccurate in phyllodes tumor diagnosis and is not recommended.
  - Treatment is wide local excision. Axillary lymph node dissection is not necessary. It has a predilection for local recurrence following local excision.
  - If biopsy establishes a diagnosis of **malignant phyllodes** (cystosarcoma phyllodes), it should be treated as a soft tissue sarcoma. See **Sarcomas – Bone, Soft Tissue, and GIST (ONC-12)** in the Oncology Imaging Guidelines.

Nipple Discharge/Galactorrhea (BR-6)

Guideline

Nipple Discharge/Galactorrhea (BR-6.1)

Nipple Discharge/Galactorrhea (BR-6.1)

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v1.0.2024

- Pathologic nipple discharge
  - Initial imaging should include diagnostic mammogram and ultrasound (CPT® 76641: unilateral, complete; or, CPT® 76642: unilateral, limited). If these are negative or inconclusive, MRI Breast is the next appropriate imaging study.
- Physiologic nipple discharge
  - If nipple discharge is physiologic, there are no suspicious findings on clinical exam, and mammogram and ultrasound are negative, no additional imaging is necessary, and the individual can be reassured.

Background and Supporting Information

- Physiologic nipple discharge is predominantly bilateral but may be unilateral. It is commonly multi-duct. It is predominantly milky but may be white or a variety of colors including serous, yellow, green, brown, or gray. Evaluation for hyperprolactinemia can be considered.
- For milky discharge, prolactin and TSH levels are recommended to diagnose prolactinoma; pituitary imaging is not needed if normal serum Prolactin.
- Pathologic nipple discharge is defined as unilateral, bloody or serous, arising from a single duct, persistent, and spontaneous.

Breast Pain (Mastodynia) (BR-7)

Guideline

Breast Pain (Mastodynia) (BR-7.1)

Breast Pain (Mastodynia) (BR-7.1)

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v1.0.2024

- Evaluation of breast pain requires a history and physical exam.
- Mammogram and ultrasound are the initial imaging for breast pain.
- Advanced imaging is **NOT** routinely indicated in individuals with breast pain and negative mammogram and ultrasound (CPT® 76641: unilateral, complete; or, CPT® 76642: unilateral, limited).
  - If mammogram and ultrasound are not negative, see **MRI Breast Indications (BR-5)**.

Background and Supporting Information

- The risk of malignancy following a negative clinical examination (clinical breast exam, mammogram, ultrasound) has been estimated to be only 0.5%.

Alternative Breast Imaging Approaches (BR-8)

Guideline

Alternative Breast Imaging Approaches (BR-8.1)

Alternative Breast Imaging Approaches (BR-8.1)

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Molecular Breast Imaging (MBI)

- Molecular Breast Imaging (CPT® 78800) is supported in individuals who meet criteria for breast cancer screening with MRI (per BR-5) but for whom MRI is contraindicated.
  - o See **MRI Breast Indications (BR-5)**

Other Alternative Breast Imaging Techniques

- Other alternative breast imaging techniques may have FDA approval, they are usually not appropriate and not supported with respect to **BOTH** screening and diagnosis of breast cancer. These include the following:
- Nuclear breast imaging, including:
  - o Scintimammography
  - o Breast specific gamma imaging (BSGI)
- PET Mammography (PEM)
- Thermography
- Impedance Mammography
- Other techniques to detect oxygen consumption, light absorption, microwave transmission, nitrous oxide production
- CT Breast (CPT® 0633T, CPT® 0634T, CPT® 0635T, CPT® 0636T, CPT® 0637T, or CPT® 0638T)
- Cone Beam CT Breast

Background and Supporting Information

- CT Breast
  - o CT Breast is evolving and currently being studied as a mode of breast cancer detection. It remains under investigation, and is not to be used in lieu of conventional breast imaging modalities.
- Positron Emission Mammography
  - o There is currently insufficient data available to generate appropriateness criteria for this modality, and this procedure is usually not appropriate and not supported.
    - High-resolution positron-emission mammography (PEM) by Naviscan™ PET Systems, also referred to as Naviscan™ or PET mammography, performs high- resolution metabolic imaging for breast cancer using an FDG tracer. The PEM detectors are integrated into a conventional mammography system, allowing acquisition of the emission images immediately after the mammogram.
    - Requesting providers often ask for PEM as CPT® 78811 or “PET scan of the breast.”

- The spatial resolution of this technique is at the individual duct level (1.5 mm) and allows visualization of intraductal as well as invasive breast cancers. This technique is especially adept at detecting ductal carcinoma in situ.
- Early clinical trials have shown high clinical accuracy in characterizing lesions identified as suspicious on conventional imaging or physical examination, as well as in detecting incidental breast cancers not seen on other imaging modalities.

- A prospective multi-center clinical trial for females with newly diagnosed breast cancer anticipating breast-conservation surgery was performed. These females underwent both high-resolution PEM imaging and breast MRI. Results showed that PEM and MRI had comparable breast-level sensitivity, although MRI had greater lesion-level sensitivity and more accurately depicted the need for mastectomy. PEM had greater specificity at the breast and lesion levels. Of these, 3.6% of the females had tumors seen only with PEM.
- The radiation exposure from a PEM study is 23 times higher than for digital mammography.

Suspected Breast Cancer in Males (BR-9)

Guideline

Suspected Breast Cancer in Males (BR-9.1)

Suspected Breast Cancer in Males (BR-9.1)

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v1.0.2024

See **Breast Ultrasound (BR-1)**

- There is limited evidence on the use of MRI in the evaluation of male breast disease.
- Further diagnostic pathway for suspicious clinical or imaging findings usually requires tissue diagnosis.

Background and Supporting Information

- Breast cancer in males presents as a mass, skin/nipple change, or pathologic nipple discharge.

Breast Evaluation in Pregnant or Lactating Females (BR-10)

Guideline

Breast Evaluation in Pregnant or Lactating Females (BR-10.1)

Breast Evaluation in Pregnant or Lactating Females (BR-10.1)

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- Breast US (CPT® 76641 or CPT® 76642) is first-line imaging in pregnant and lactating females.
- If pregnant/lactating female has a palpable mass **OR** has persistent unilateral bloody nipple discharge and US is negative or suspicious, follow with diagnostic mammogram (with lead abdominal shielding).
- IV Gadolinium is required with MRI to evaluate breast parenchyma but is contraindicated in pregnancy. Biopsy, rather than advanced imaging, is recommended after inconclusive mammogram and US.

Transgender Breast Cancer Supplemental Screening (BR-12)

Guideline

Transgender Breast Cancer Supplemental Screening (BR-12.1)

Transgender Breast Cancer Supplemental Screening (BR-12.1)

BR.TS.0012.1.A
v1.0.2024

- Annual supplemental Ultrasound **AND/OR** MRI Breast screening is indicated for the following:
  - Transmasculine (female-to-male) with ALL of the following risk factors:
    - Reduction mammoplasty or no chest surgery
    - Age ≥25
    - High-risk (≥20% lifetime risk)
- Annual Ultrasound and/or MRI Breast, in addition to mammogram, for breast cancer screening is **NOT indicated** in any other scenarios, including **ANY** of the following:
  - Transfeminine (male-to-female)
  - Transmasculine (female-to-male), who have had bilateral mastectomies
  - Transmasculine (female-to-male), who have **NOT** had mastectomies **AND** are at average risk or intermediate risk
- Acceptable models of calculating clinical lifetime-risk include the following: Gail (NCI), Claus, Tyrer-Cuzick (IBIS), or BRCAPRO.

3D Rendering (BR-13)

Guideline

3D Rendering (BR-13.1)

3D Rendering (BR-13.1)

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- 3D rendering (CPT® 76376 or CPT® 76377) should **NOT** be used in conjunction with **ANY** 3D mammography code.
- 3D rendering (CPT® 76376 or CPT® 76377) is **NOT** indicated for breast ultrasound. It is commonly requested in conjunction with automated breast ultrasound (ABUS); there is no evidence to support its clinical usefulness.
- 3D rendering (CPT® 76376 or CPT® 76377) should **NOT** be used in conjunction with MRI Breast.

References (BR)

Guideline

References (BR)

References (BR)

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Guideline

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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

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