

# UNITEDHEALTHCARE® COMMUNITY PLAN: RADIOLOGY IMAGING COVERAGE DETERMINATION GUIDELINE

### Adult Pelvis Imaging Guidelines (For Ohio Only)

V1.0.2026

Guideline Number: CSRAD0110H.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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#### **General Policies**

- · General Abdomen Imaging Guidelines
- General Oncology Imaging Guidelines

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Pediatric Pelvis Imaging Guidelines

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## **Application (For Ohio Only)**

#### **Application for Ohio OH UHC**

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# Guideline Development (Preface-1)

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Guideline Development (Preface-1.1)

## **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.

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

#### Guideline

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 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)

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Clinical Information (Preface-3.1) References (Preface-3)

## 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<sup>®</sup> 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<sup>®</sup> 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).</li>
- 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<sup>®</sup> 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).</li>
  - 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:

- 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<sup>®</sup> 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)

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

Unlisted Procedures/Therapy Treatment Planning (Preface-4.3)

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

SPECT/CT Imaging (Preface-4.6)

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

Quantitative MR Analysis (Preface-4.8)

HCPCS Codes (Preface-4.9)

References (Preface-4)

## 3D Rendering (Preface-4.1)

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#### CPT<sup>®</sup> 76376 and CPT<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 77011 or CPT<sup>®</sup> 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<sup>®</sup> 76377 (3D rendering requiring image post-processing on an independent workstation) or CPT<sup>®</sup> 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 preoperative planning when conventional imaging is insufficient)
    - Spine fractures, pelvic/acetabulum fractures, intra-articular fractures (for preoperative 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 <u>Abnormal Uterine</u> <u>Bleeding (AUB) (PV-2.1)</u> and <u>Leiomyoma/Uterine Fibroids (PV-12.1)</u> 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 <u>Intrauterine</u>
       <u>Device (PV-10.1)</u> in the Pelvis Imaging Guidelines.
    - Uterine anomalies with initial US: See <u>Uterine Anomalies (PV-14.1)</u> in the Pelvis Imaging Guidelines.
    - Infertility: See <u>Initial Infertility Evaluation</u>, <u>Female (PV-9.1)</u> in the Pelvis Imaging Guidelines.
  - Abdomen conditions:
    - CT Urogram: See <u>Hematuria and Hydronephrosis (AB-39)</u> in the Abdomen Imaging Guidelines.
    - MRCP: See <u>MR Cholangiopancreatography (MRCP) (AB-27)</u> in the Abdomen Imaging Guidelines.

# 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<sup>®</sup> 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<sup>®</sup> 19086.
  - CPT® 77021 (MR guidance for needle placement) is not an appropriate code for a breast biopsy.

#### **CPT<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 70486 and CPT<sup>®</sup> 77011 for the same CT stereotactic localization imaging session.
  - 3D Rendering (CPT<sup>®</sup> 76376 or CPT<sup>®</sup> 76377) should not be reported in conjunction with CPT<sup>®</sup> 77011 (or CPT<sup>®</sup> 70486 if used). The procedure inherently generates a 3D dataset.

#### CPT<sup>®</sup> 77012 (CT) and CPT<sup>®</sup> 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<sup>®</sup> 19085 would be appropriate for the first breast biopsy site and CPT<sup>®</sup> 19086 would be appropriate for additional concurrent biopsies.

#### CPT<sup>®</sup> 77013 (CT) and CPT<sup>®</sup> 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<sup>®</sup> 77013 should only be used for non-bone ablation procedures.
    - CPT<sup>®</sup> 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<sup>®</sup> 77012 and CPT<sup>®</sup> 77021 (as well as guidance codes CPT<sup>®</sup> 76942 [US], and CPT<sup>®</sup> 77002 CPT<sup>®</sup> 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)

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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 <u>Management</u> 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<sup>®</sup> 76497 or CPT<sup>®</sup> 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 <u>Navigational Bronchoscopy and Biopsy</u> (<u>CH-1.7</u>) in the Chest Imaging Guidelines.

#### **Therapy Treatment Planning**

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

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

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- CPT<sup>®</sup> 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<sup>®</sup> 76380) is not medically necessary for treatment planning purposes. See <u>Unlisted Procedure Codes in Oncology (ONC-1.5)</u> in the Oncology Imaging Guidelines.
- It is inappropriate to report CPT<sup>®</sup> 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<sup>®</sup> code definition.
  - The AMA, in  $CPT^{\otimes}$  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 <sup>123</sup>I- or <sup>131</sup>I-Metaiodobenzylguanidine (MIBG) and octreotide scintigraphy for neuroendocrine tumors.
- Hybrid Nuclear/CT scan can be reported as CPT<sup>®</sup> 78830 (single area and single day), CPT<sup>®</sup> 78831 (2 or more days), or CPT<sup>®</sup> 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

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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.

## **Quantitative MR Analysis (Preface-4.8)**

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- Category III CPT<sup>®</sup> 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.

## **HCPCS Codes (Preface-4.9)**

PRF.CD.0004.9.UOH

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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<sup>®</sup> codes, those procedures should be managed in the same manner as the typical CPT<sup>®</sup> 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], lowfield), should be redirected to a more appropriate and specific CPT® code. Exceptions are noted in the applicable guideline sections.

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### References (Preface-4)

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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 <u>Multiple Myeloma and Plasmacytomas (ONC-25)</u> 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<sup>®</sup> 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<sup>®</sup> 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 <u>Li-Fraumeni Syndrome (LFS)</u> (PEDONC-2.2), <u>Neurofibromatosis 1 and 2 (NF1 and NF2) (PEDONC-2.3)</u>, <u>Rhabdoid Tumor Predisposition Syndrome (PEDONC-2.11)</u>, <u>Hereditary Paraganglioma-Pheochromocytoma (HPP) Syndromes (PEDONC-2.13)</u>, <u>Constitutional Mismatch Repair Deficiency (CMMRD or Turcot Syndrome) (PEDONC-2.15)</u>, <u>Infantile Myofibromatosis (PEDONC-2.18)</u>, or <u>Bloom Syndrome (PEDONC-2.19)</u> 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 <u>Multiple Myeloma and Plasmacytomas (ONC-25)</u> 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	t Multifocal Osteomyelitis
(PEDMS-10.2) in the Pediatric Musculoskeletal Ima	aging 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<sup>®</sup> 78813) and MRI Unlisted (CPT<sup>®</sup> 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.

### References (Preface-5)

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## References (Preface-6)

Guideline

References (Preface-6.1)

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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 (PV-1)

#### Guideline

Abbreviations for Pelvis Imaging Guidelines General Guidelines (PV-1.0) General Guidelines – Overview (PV-1.1) References (PV-1)

## **Abbreviations for Pelvis Imaging Guidelines**

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Abbreviations for Pelvis Imaging Guidelines				
CA-125	cancer antigen 125 test			
СТ	computed tomography			
FSH	follicle-stimulating hormone			
GTN	gestational trophoblastic neoplasia			
HCG	human chorionic gonadotropin			
IC/BPS	interstitial cystitis/bladder pain syndrome			
IUD	intrauterine device			
KUB	kidneys, ureters, bladder (frontal supine abdomen radiograph)			
LH	luteinizing hormone			
MRA	magnetic resonance angiography			
MRI	magnetic resonance imaging			
MSv	millisievert			
PA	posteroanterior projection			
PID	pelvic inflammatory disease			
TA	transabdominal			
TSH	thyroid-stimulating hormone			

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Abbreviations for Pelvis Imaging Guidelines				
TV	transvaginal			
UCPPS	Urologic Chronic Pelvic Pain Syndrome			
WBC	white blood cell count			

## **General Guidelines (PV-1.0)**

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- A current clinical evaluation since the onset or change in symptoms is required before advanced imaging can be considered. The clinical evaluation should include a relevant history and physical examination including a pelvic and/or urological exam, appropriate laboratory studies, and non-advanced imaging modalities such as plain x-ray or Pelvic ultrasound (CPT® 76856 or CPT® 76857) and/or Transvaginal ultrasound (CPT® 76830) and/or Transperineal ultrasound (CPT® 76872).
  - Other meaningful contact (telehealth visit, telephone call, electronic mail or messaging) since the onset or change in symptoms for follow up visit by an established individual can substitute for a face-to-face clinical evaluation.
- The use of gynecology CPT codes for pregnant females is not supported. Therefore, transvaginal ultrasound (CPT® 76830) and pelvic ultrasound (CPT® 76856 or CPT® 76857) are not medically necessary for those with a positive pregnancy test or known pregnancy. If a pregnancy test is positive, then obstetrical CPT codes are medically necessary.
- Abdominal imaging begins at the diaphragm and extends to the umbilicus or iliac crest.
- Pelvic imaging begins at the iliac crest and extends to the pubis.
- The uterus, tubes and ovaries arise out of the pelvis and are considered pelvic organs. If the uterus or adnexa rise out of the pelvic cavity, above the level of the iliac crest or umbilicus on physical exam or on previous imaging, abdominal imaging may be added for the completion of imaging.
- MRI (MRI Pelvis without contrast CPT® 72195) for Defecography is considered investigational/experimental by UHC.

#### **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.

### General Guidelines – Overview (PV-1.1)

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 When medically necessary, pregnant females should be evaluated with ultrasound or MRI without contrast to avoid radiation exposure. In carefully selected clinical circumstances, evaluation with CT may be medically necessary with careful attention to technique and radiation protection as deemed clinically appropriate.

#### **Ultrasound**

- Transvaginal ultrasound is the standard modality for imaging; no alternative modality has demonstrated sufficient superiority to justify routine use, and Transvaginal (TV) ultrasound (CPT® 76830) is the optimal study to evaluate adult female pelvic organ pathology.
- Pelvic ultrasound (complete CPT® 76856, or limited CPT® 76857) is medically necessary if it is a complementary study to the TV ultrasound. It may substitute for TV in pediatric individuals or non-sexually active females.
- Transperineal ultrasound (CPT® 76872) is medically necessary for cases of suspected urethral abnormalities, urinary incontinence, pelvic prolapse, or vaginal cysts.
- CPT® 76942 is used to report ultrasound imaging guidance for needle placement during biopsy, aspiration, and other percutaneous procedures.

#### Soft Tissue Ultrasound

Pelvic wall, buttocks, and penis - CPT® 76857

#### **Scrotal Ultrasound**

- See
  - Impotence/Erectile Dysfunction (PV-17.1)
  - Penis-Soft Tissue Mass (PV-18.1)
- Ultrasound scrotum and contents CPT 76870

#### 3D Rendering with Ultrasound

- 3D Rendering (CPT® 76376 or CPT® 76377)
  - CPT® 76377 (3D rendering requiring image post-processing on an independent work station) or CPT®

76376 (3D rendering not requiring image post-processing on an independent workstation) in the following clinical scenarios is medically necessary:

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- Uterine intra-cavitary lesion when initial ultrasound is equivocal (See <u>Abnormal</u> Uterine Bleeding (AUB) (PV-3.1) and Leiomyoma/Uterine Fibroids (PV-12.1)
- Hydrosalpinges or peritoneal cysts when initial ultrasound is equivocal (See Complex Adnexal Masses (PV-5.3))
- Lost IUD (inability to feel or see IUD string) with initial ultrasound (See Intrauterine Device (PV-10.1)
- Uterine anomaly is suspected on ultrasound (See Uterine Anomalies (PV-14.1))
- Infertility if ultrasound is indeterminate or there is clinical suspicion for intracavitary lesion (such as polyp or fibroid), hydrosalpinx, uterine synechia, adenomyosis or uterine anomalies (See Initial Infertility Evaluation, Female (PV-9.1)
- 3D-4D (CPT® 76376 or CPT® 76377) rendering is medically necessary in certain situations of abnormal pregnancy implantation like suspected C-section scar pregnancies or suspected cornual (interstitial) ectopic pregnancy, or to locate an IUD.
- 3D-4D (CPT® 76376 or CPT® 76377) rendering is medically necessary for surgical planning with diagnosis of complex CHD in the fetus or for surgical planning of other complex fetal malformations.

#### Other Ultrasound

- CPT® 93975 Duplex scan (complete) of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study.
- CPT® 93976 Duplex scan (limited) of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; limited study.
- CPT® 93975 and CPT® 93976 should not be reported together during the same session.

#### CT

· CT is not medically necessary for evaluating pelvic anatomy because it is limited due to soft tissue contrast resolution.

#### MRI

- Is medically necessary when used as a more targeted study or for individuals allergic to iodinated contrast.
  - MRI Pelvis without contrast (CPT® 72195)
  - MRI Pelvis without and with contrast (CPT® 72197)
  - MRI Pelvis with contrast only (CPT® 72196) is rarely performed

#### **Evidence Discussion (PV-1.1)**

- Ultrasonography and magnetic resonance imaging (MRI) are the imaging techniques of choice for the pregnant individual, they should be used prudently and only when use is expected to answer a relevant clinical question 11.
- CT is not generally warranted for evaluating pelvic anatomy because it is limited due to soft tissue contrast resolution. Computed tomography (CT) scans are generally not recommended during pregnancy unless the benefits clearly outweigh the potential risks<sup>12</sup>. Computed tomography (CT) scan if necessary in addition to ultrasonography or MRI if more readily available for the diagnosis in question, should not be withheld from a pregnant individual. The risk of adverse effects from ionizing radiation should always be weighed against the risk of not performing the procedure and the benefit derived from the procedure<sup>12</sup>.
- Ultrasound is the recommended modality for imaging the female pelvic organs; no alternative modality has demonstrated sufficient superiority to justify routine use<sup>3</sup>, and transvaginal ultrasound is the optimal study to evaluate adult female pelvic pathology. Transabdominal pelvic ultrasound is a useful complementary study to transvaginal ultrasound and may substitute for transvaginal ultrasound in pediatric individuals or non-sexually active females. The American Institute of Ultrasound in Medicine (AIUM.org) launched an initiative in 2012 "Ultrasound First," which advocates the use of ultrasound examinations before other imaging modalities when the evidence shows that ultrasound imaging is at least equally, if not more, effective for the target anatomic area 13. This applies particularly to obstetric and gynecologic patients for whom a skillfully performed and well-interpreted ultrasound image usually obviates the need to proceed to additional more costly and complex cross-sectional imaging techniques<sup>3</sup>.
- Transperineal ultrasound can be useful for cases of suspected urethral abnormalities, urinary incontinence, pelvic prolapse, or vaginal cysts <sup>14,15</sup>. A study by Yang, et al confirmed transvaginal or transperineal ultrasound to be a non-invasive and costeffective modality for diagnosis of urethral and periurethral masses 14. Vaginal and urethral imaging is limited on transvaginal ultrasound due to the position of the endovaginal probe rendering the vagina out of the field, on computed tomography (CT) due to poor soft tissue discrimination of the vaginal walls and on magnetic resonance imaging (MRI). MRI of the vagina should be done with thin slice thickness and proper choice of the degree of angulation and used MR sequence, otherwise there is limited evaluation of the vagina 15. Transperineal ultrasound is also a dynamic real-time examination, and can detect subtle abnormalities that are not seen in static imaging<sup>15</sup>.
- Scrotal ultrasound is supported for evaluation of scrotal pain or suspected mass 16,17. The American Urological Association recommends scrotal ultrasound for initial evaluation of unilateral or bilateral scrotal mass suspicious for neoplasm<sup>17</sup>.
- Three-dimensional (3D) rendering with ultrasound can be considered when ultrasound shows suspected uterine anomaly, uterine intra-cavitary lesion,

- hydrosalpinges or peritoneal cysts<sup>2,4,5,6</sup>. A study by Laskshmy et al found 3D ultrasound to be a highly sensitive and specific tool for accurately diagnosing congenital uterine anomalies<sup>2</sup>. 3D rendering has shown a high degree of concordance with MRI and laparoscopy for congenital uterine anomalies, and is noninvasive, readily available and relatively cost-effective<sup>4</sup>. Three-dimensional ultrasound is a noninvasive method for evaluation of adnexal pathology 18.
- Doppler scan can be of benefit in addition to ultrasound for further evaluation of suspected uterine or ovarian abnormalities. Doppler flow mapping is useful in diagnosing submucosal fibroids and endometrial polyps<sup>19</sup>. ACOG (American College of Obstetrics and Gynecology)recommended that color Doppler ultrasonography is useful to evaluate the vascular characteristics of adnexal masses<sup>1</sup>. MRI pelvis is useful in cases such as inconclusive ultrasound for adenomyosis. "MRI is a second-line examination in the diagnosis of internal adenomyosis, mainly after a nonconclusive US evaluation. In addition, MRI can differentiate between the subtypes of adenomyosis." MRI pelvis is also useful for further evaluation of indeterminate adnexal masses. A study by Dirrichs, et al found MRI to improve sensitivity and specificity of diagnosis of indeterminate adnexal masses detected at TVUS, and use of MRI changed therapeutic management in 34% of cases<sup>21</sup>. MRI can aid in the diagnosis of deep pelvic endometriosis<sup>22</sup>. MRI pelvis is useful for further evaluation of unexplained pelvis pain when ultrasound evaluation is inconclusive<sup>23</sup>. Pelvic MRI is useful for evaluation of fibroids prior to uterine-sparing interventional techniques. "Although a high-quality ultrasonography (US) examination may be sufficient for evaluation in patients with straightforward cases of fibroids (for instance to estimate the size of a dominant fibroid), imaging evaluation is most reliably performed with magnetic resonance (MR) imaging to determine the characteristics, number, size, and location of fibroids and to assess for other pathologic conditions such as adenomyosis."24
- There is currently insufficient data to generate appropriateness criteria for the use of 3D and 4D rendering in conjunction with Obstetrical ultrasound imaging. Per ACOG, proof of a clinical advantage of 3-dimensional ultrasonography in prenatal diagnosis, in general, is still lacking.

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## **Abnormal Uterine** Bleeding (PV-2)

#### Guideline

Abnormal Uterine Bleeding (AUB) (PV-2.1) Retained Products of Conception (PV-2.2) References (PV-2)

# Abnormal Uterine Bleeding (AUB) (PV-2.1)

PV.UB.0002.1.UOH

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- Pregnancy test should be done initially if premenopausal
- If pregnancy test is negative or post menopausal initial evaluation includes ANY or ALL of the following:
  - Pelvic ultrasound (CPT® 76856 or CPT® 76857) and/or Transvaginal ultrasound (CPT® 76830), D&C and/or endometrial biopsy
- Advanced imaging is not medically necessary for Endometrial Intraepithelial Neoplasia or Atypical Endometrial Hyperplasia (EIN-AEH) as imaging has not been found to improve outcomes for this condition.
- · In females with postmenopausal bleeding
  - Those with thickened endometrium on ultrasound, those whose ultrasound failed to identify a thin, distinct endometrial strip and/or those with continued vaginal bleeding should all undergo endometrial biopsy to rule out endometrial carcinoma
- If biopsy confirms a malignancy, then see the appropriate oncology guideline.
- If ultrasound is equivocal for intracavitary lesion the following is medically necessary:
  - Duplex (Doppler) scan (CPT® 93975 complete; CPT® 93976 limited) as an add-on to TV ultrasound (CPT® 76830).
  - 3-D Rendering (CPT® 76377 or CPT® 76376) as an add-on.
- CT is not generally warranted for evaluating AUB since uterine anatomy is limited due to soft tissue contrast resolution.
  - An abnormal endometrium found incidentally on CT should be referred for TV ultrasound for further evaluation.
- MRI is not indicated for evaluation of abnormal uterine bleeding, please see specific Pelvis Imaging sections for MRI indications for ultrasound findings such as adnexal mass or uterine fibroids. See <u>Adnexal Mass/Ovarian Cysts (PV-5)</u> and <u>Leiomyomata (PV-12.1)</u>.

#### **Evidence Discussion (PV-2.1)**

Transabdominal pelvic and/or transvaginal pelvic ultrasound are widely accepted as
the initial imaging modality of choice for evaluation of abnormal uterine bleeding<sup>2,12</sup>.
Ultrasound also allows for real-time evaluation with color and power Doppler which
can help identify vascular flow and distinguish fluid and cysts from soft tissue<sup>12</sup>.
Additional benefits to ultrasound as a first line imaging modality include wide
availability, fast access, and lack of ionizing radiation exposure. 3-D Rendering has

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- been shown to a useful adjunct for analysis of suspected lesions the endometrial cavity.
- MRI is not supported as an initial imaging modality for the diagnosis of abnormal uterine bleeding<sup>12</sup>. While MRI is accepted as an adjunct modality to ultrasound in cases where ultrasound may not fully characterize a soft tissue abnormality, imaging should be directed by the type of suspected soft tissue abnormality (i.e. adenomyosis, endometriosis, fibroids, and adnexal mass) and is addressed in additional sections of these guidelines. CT is of limited use in the evaluation of abnormal uterine bleeding given its suboptimal evaluation of the soft tissue of female pelvic organs<sup>12</sup>.
- In premenopausal women presenting with abnormal uterine bleeding a pregnancy test should be performed. For those with a positive pregnancy test, imaging with appropriate obstetric ultrasound should be performed.
- Vaginal bleeding is the presenting symptom in 90% of postmenopausal women with endometrial cancer<sup>10</sup>. An endometrial strip of 4mm or less on ultrasound has been found to have a greater than 99% negative predictive value for endometrial cancer<sup>10</sup>. However, this cutoff may be inadequate in Black women, as it missed five-fold more cases than in White women<sup>13</sup>. Endometrial tissue sampling remains the gold standard for diagnosis of endometrial carcinoma. As such, those with thickened endometrium on ultrasound, those who ultrasound failed to identify a thin, distinct endometrial strip and those with continued vaginal bleeding should all undergo endometrial sampling to rule out endometrial carcinoma<sup>10</sup>.
- The incidence of concurrent endometrial cancer with the diagnosis of Endometrial Intraepithelial Neoplasia or Atypical Endometrial Hyperplasia (EIN-AEH) is approximately 30% to 50%<sup>1</sup>. This makes evaluation for concurrent carcinoma imperative in the diagnosis of EIN-AEH for those considering a fertility-sparing treatment. The most accurate method for diagnosis is hysteroscopic-guided uterine sampling<sup>1</sup> which has the added benefit of direct visualization of any intrauterine pathology such as endometrial polyps.

## **Retained Products of Conception** (PV-2.2)

PV.UB.0002.2.A

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- · For abnormal uterine bleeding and/or pelvic pain with concern for retained products of conception (RPOC):
  - Pelvic ultrasound (CPT® 76856 or CPT® 76857) and/or Transvaginal ultrasound (CPT® 76830) is medically necessary one time, repeat US is medically necessary for continued symptoms
  - Color Doppler ultrasonography (CPT® 93975 or CPT® 93976) may be added to ultrasound to aid in diagnosis of RPOC
  - CT Pelvis with and without contrast (CPT® 72194) OR MRI Pelvis with and without contrast (CPT® 72197) is medically necessary if US with Color Doppler is equivocal AND further imaging is needed for surgical planning

#### **Evidence Discussion (PV-2.2)**

- Transabdominal pelvic and/or transvaginal pelvic ultrasound are widely accepted as the initial imaging modality of choice for evaluation of suspected retained products of conception (RPOC)<sup>15,16</sup>. Ultrasound also allows for real-time evaluation with color and power Doppler which can help identify vascular flow within the endometrial complex, which improves the specificity and negative predictive value of detecting RPOC<sup>15</sup>. Additional benefits to ultrasound as a first line imaging modality include wide availability, fast access, and lack of ionizing radiation exposure.
- For most cases ultrasound is sufficient for detection of RPOC. For cases where ultrasound is inconclusive additional imaging with MRI or CT may provide additional information to aid in surgical planning 16.

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## Amenorrhea (PV-3)

#### Guideline

Secondary Amenorrhea (PV-3.1) Primary Amenorrhea (PV-3.2) References (PV-3)

## Secondary Amenorrhea (PV-3.1)

PV.AM.0003.1.A

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- Pregnancy test should be done initially
- If a pregnancy test is positive:
  - Refer to the member's individual coverage policy regarding obstetrical imaging indications and appropriate obstetrical imaging procedural codes. Billing of gynecology codes during pregnancy is not supported.
- If a pregnancy test is negative, further evaluation includes any of the following:
  - FSH, TSH, estradiol, and/or prolactin levels are medically necessary depending on clinical suspicion.
  - Serum free and total testosterone and/or DHEAS levels are indicated if there is evidence of hyperandrogenism
  - Pelvic ultrasound (CPT® 76856 or CPT® 76857) and/or TV ultrasound (CPT® 76830) for suspected uterine or ovarian pathology are medically necessary
- The results of test(s) above determine the next steps, which include:
  - For suspected adrenal tumor, See <u>Adrenal Cortical Lesions (AB-16)</u> in the Abdomen Imaging Guidelines.
  - For suspected pituitary tumor or hypothalamic, See <u>Pituitary</u>, <u>Sella</u>, <u>Hypothalamus(HD-19)</u> in the Head Imaging Guidelines
  - For suspected Asherman's Syndrome the following are medically necessary:
    - Hysterosalpingogram (CPT® 74740), sonohysterosalpingography (CPT® 76831), and/or hysteroscopy if ultrasound is indeterminate for Asherman's syndrome
    - MRI Pelvis without contrast (CPT® 72195) or without and with contrast (CPT® 72197) if hysterosalpingogram (CPT® 74740), sonohysterosalpingography (CPT® 76831), or hysteroscopy is indeterminate for Asherman's Syndrome.

#### **Background and Supporting Information**

 Asherman's syndrome: an acquired condition which refers to having scar tissue in the uterus

## **Primary Amenorrhea (PV-3.2)**

PV.AM.0003.2.A

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- Prior to imaging a history, physical examination and Tanner stage should be evaluated.
- Initial evaluation may include pelvic ultrasound (CPT® 76856 or CPT® 76857) and/or TV ultrasound (CPT® 76830) as medically necessary if ANY of the following:
  - Normal pubertal development and negative pregnancy test
  - Pelvic exam is indeterminate or unable to be performed
  - Delayed puberty with follicle-stimulating hormone (FSH) or luteinizing hormone (LH) that is elevated for the individual's age and Tanner stage
- If ultrasound defines a uterine or vaginal anomaly see **Uterine Anomalies (PV-14.1)**
- For suspected pituitary or hypothalamic tumor, See Pituitary, Sella, Hypothalamus (HD-19) in the Head Imaging Guidelines

#### **Background and Supporting Information**

- Evaluation of an individual without a uterus (determined by imaging or examination) may include karyotype and/or testosterone levels.
- TV ultrasound (CPT® 76830) is medically necessary in pediatric individuals who are sexually active or use a tampon and consent to the study.

#### **Evidence Discussion (PV-3)**

- The initial work up of amenorrhea should include a physical exam, pregnancy test and hormonal work up. For those with a positive pregnancy test, imaging with obstetric ultrasound should be performed. Hormonal testing can help to further direct imaging $^{7,2,5,6}$ .
- · Transabdominal pelvic and/or transvaginal pelvic ultrasound are widely accepted as the initial imaging modality of choice for evaluation of amenorrhea<sup>7,2,5,6</sup>. Ultrasound also allows for real-time evaluation with color and power Doppler which can help identify vascular flow and distinguish fluid and cysts from soft tissue'. Additional benefits to ultrasound as a first line imaging modality include wide availability, fast access, and lack of ionizing radiation exposure.
- MRI is supported as an adjunct to inconclusive ultrasound imaging, especially if the ultrasound is suggestive of a congenital uterine or vaginal anomaly. CT is of limited use in the evaluation of amenorrhea given its suboptimal evaluation of the soft tissue of female pelvic organs.
- For suspected Asherman's syndrome, the gold standard for diagnosis remains hysteroscopy which has the added benefit of allowing for simultaneous treatment of adhesive disease<sup>8,9</sup>. However, hysteroscopy carries with it risks of anesthesia and

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uterine perforation. Hysterosaplingogram (HSG) allows for simultaneous evaluation of tubal patency<sup>8</sup>. Sonohsyterography (SHG) has a high negative predictive value (98%), but only a modest positive predictive value (43%)8. MRI may be a useful adjunct to HSG, SHG and hysteroscopy, especially in cases where there is complete obstruction of the endometrial cavity limiting the diagnostic ability of these tests<sup>8,9</sup>.

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## Adenomyosis (PV-4)

Guideline

Adenomyosis (PV-4.1) References (PV-4)

## Adenomyosis (PV-4.1)

PV.AD.0004.1.A

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- TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76856 or CPT® 76857) is the medically necessary diagnostic procedure of choice for the initial evaluation of suspected adenomyosis. Duplex Doppler (CPT® 93975 or CPT® 93976) can be added if requested.
- MRI Pelvis without contrast (CPT® 72195) or MRI Pelvis without and with contrast (CPT® 72197) is considered a medically necessary second-line imaging option after transvaginal ultrasound if:
  - Diagnosis is inconclusive for adenomyosis after an ultrasound and further delineation would affect management
  - MRI needed to guide the treatment of adenomyosis in an individual with an enlarged uterus, and coexisting leiomyoma/fibroid following indeterminate ultrasound
  - Uterine artery embolization is being considered
    - If MRI is equivocal, MRA Pelvis (CPT® 72198) or CTA Pelvis (CPT® 72191) if requested by or in consultation with the interventional radiologist planning the uterine artery embolization

#### **Background and Supporting Information**

Adenomyosis is when endometrial tissue, which normally lines the uterus, moves into the outer muscular walls of the uterus. Adenomyosis is a histologic diagnosis and is suspected by history and physical examination. Ultrasound findings of adenomyosis include heterogeneous myometrium, myometrial cysts, asymmetric myometrial thickness, and subendometrial echogenic linear striations.

#### **Evidence Discussion (PV-4.1)**

• Transabdominal pelvic and/or transvaginal pelvic ultrasound are widely accepted as the initial imaging modality of choice for evaluation of adenomyosis <sup>10,1,2,3</sup>. Ultrasound also allows for real-time evaluation with color and power Doppler which can help identify vascular flow and distinguish fluid and cysts from soft tissue <sup>10</sup>. In the presence of features mimicking leiomyomas, Doppler US displaying vessels perpendicular to the endometrial interface, is suggestive of adenomyosis <sup>2</sup>. Transvaginal ultrasound has a sensitivity of 83.8% and specificity of 63.9% for adenomyosis <sup>7,8</sup>. The overall diagnostic accuracy of the use of transvaginal ultrasound with color Doppler for adenomyosis is 93.8% Additional benefits to ultrasound as a first line imaging modality include wide availability, fast access, and lack of ionizing radiation exposure.

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MRI of the pelvis is a second-line examination in the diagnosis of adenomyosis. mainly after an inconclusive US evaluation<sup>2</sup>. MRI pelvis is useful in individuals with coexisting leiomyoma<sup>2</sup>. A meta-analysis comparing the diagnostic performance of MRI and transvaginal ultrasound reported that MRI had a pooled sensitivity of 77% and a specificity of 89%<sup>2</sup>. The authors concluded that MRI performs more favorably than transvaginal ultrasound in the presence of associated uterine leiomyomas<sup>2</sup>.

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## Adnexal Mass/ Ovarian Cysts (PV-5)

#### Guideline

Suspected Adnexal Mass – Initial Evaluation (PV-5.1)
Simple Cysts (PV-5.2)
Complex Adnexal Masses (PV-5.3)
Screening for Ovarian Cancer/Suspected Ovary Cancer (PV-5.4)
References (PV-5)

# Suspected Adnexal Mass – Initial Evaluation (PV-5.1)

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- A potential mass is found on exam and/or found incidentally on other imaging
- Transvaginal (TV) ultrasound imaging (CPTCPT® 76830) is the medically necessary initial study of choice.
  - Pelvic ultrasound (CPT® 76856 or CPT® 76857) can be performed if requested as a complimentary study to the TV ultrasound.
  - Once confirmed, Color Doppler ultrasonography (CPT® 93975 or CPT® 93976) may be medically necessary to evaluate the vascular characteristics of adnexal masses.
- MRI Pelvis without contrast (CPT® 72195), OR without and with contrast (CPT® 72197; CPT® 72195 if pregnant) is medically necessary if ultrasound does not identify the origin of the pelvic mass (adnexal, uterine, or other in etiology).
  - If the mass is unrelated to female pelvic organ anatomy, see <u>Abdominal Mass</u>
     (AB-13) in the Abdomen Imaging Guidelines.
- For O-RADS™ 0 (incomplete evaluation) either repeat ultrasound OR MRI Pelvis without contrast (CPT® 72195), OR without and with contrast (CPT® 72197)is medically necessary
  - If pregnant, MRI pelvis without contrast CPT® 72195 is medically necessary to avoid gadolinium exposure to the fetus.

#### **Background and Supporting Information**

- Consultation with or referral to a gynecologic oncologist is recommended for females with an adnexal mass who meet one or more of the following criteria:<sup>7</sup>
  - Postmenopausal with elevated CA-125 level, ultrasound findings suggestive of malignancy, ascites, a nodular or fixed pelvic mass, or evidence of abdominal or distant metastasis.
  - Premenopausal with very elevated CA-125 level, ultrasound findings suggestive of malignancy, ascites, a nodular or fixed pelvic mass, or evidence of abdominal or distant metastasis.<sup>7</sup>
  - Premenopausal or postmenopausal with an elevated score on a formal risk assessment test such as the multivariate index assay, risk of malignancy index, or the Risk of Ovarian Malignancy Algorithm or one of the ultrasound-based scoring systems from the International Ovarian Tumor Analysis group.<sup>7</sup>
- O-RADS™ 0 should not be used for masses that are completely visualized but the diagnosis is unclear.

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- Simple and Complex Adnexal Cysts
  - Simple cysts are smooth walled and clear without debris.
  - Complex cysts can have solid areas or excrescences, and/or debris in them, greater than 3mm irregular septations, mural nodules with Doppler-detected blood flow, and/or free abdominal/pelvic fluid.
- Suspected Adnexal Mass Tumor Markers
  - The adnexa include the ovaries, Fallopian tubes, and ligaments that hold the uterus in place.
  - CA-125 is a tumor marker that is useful for the evaluation of adnexal mass:
    - Elevation occurs with both malignant (epithelial cancer) and benign entities (leiomyoma, endometriosis, PID, inflammatory disease such as lupus, and inflammatory bowel disease).
    - Increase in the markers over time occurs with malignancy only
    - Consider tumor markers in individuals with an abnormal ultrasound that is not a simple cyst
  - Other markers include Beta hCG, LDH, and AFP (germ cell tumors) and Inhibin A and B (granulosa cell tumor).

## Simple Cysts (PV-5.2)

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- Simple cysts are smooth, thin walled, anechoic and clear without debris. Simple cysts up to 10 cm in diameter as measured by ultrasound are almost universally benign.
  - Repeat TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76857 or CPT® 76856) is medically necessary
    - Follow up according to the below schedule if ≤10 cm
  - Routine use of 3D rendering (CPT® 76376/CPT® 76377) for evaluation of simple ovarian cysts is not medically necessary.

#### Simple Cyst Follow-Up

Size	Pre-Menopausal	Post-Menopausal
≤3 cm	• None	• None
>3 cm to 5 cm	• None	<ul> <li>Follow-up in 12 months with TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76857 or CPT® 76856) is medically necessary:         <ul> <li>If smaller (≥10-15% decrease) no further surveillance.</li> <li>If stable follow-up TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76857 or CPT® 76856) at 24 months from initial exam</li> <li>If enlarging (≥10%-15% increase) follow-up TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76857 or CPT® 76856) at 12 and 24 months from initial exam</li> </ul> </li> <li>If there is a change in morphology on follow imaging see Complex Adnexal Masses (PV 5.3)</li> </ul>

Size	Pre-Menopausal	Post-Menopausal
>5 cm to ≤10 cm	Follow up in 8-12 weeks (proliferative phase if possible) with TV ultrasound (CPT® 76830) and/ or Pelvic ultrasound (CPT® 76857 or CPT® 76856) is medically necessary; further follow-up intervals may be adjusted on basis of degree of cyst change	<ul> <li>Follow-up in 3-6 months with TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76857 or CPT® 76856) is medically necessary; further follow-up intervals may be adjusted on basis of degree of cyst change.</li> <li>Subsequent follow up with TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76857 or CPT® 76856) is medically necessary annually and if stable for 2 years or decreasing in size, no further imaging follow-up is needed.</li> </ul>

Size	Pre-Menopausal	Post-Menopausal
>10 cm	<ul> <li>If not excised, US follow up within 6 months with TV Ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76857 or CPT® 76856) is medically necessary</li> <li>If stable, follow up Ultrasound can be done at 12 and 24 months from initial exam</li> <li>If solid component, MRI Pelvis without and with contrast (CPT® 72197) is medically necessary</li> <li>If ultrasound equivocal for Simple cyst, MRI Pelvis without and with contrast (CPT® 72197) is medically necessary</li> <li>If follow up ultrasound imaging shows changing morphology and/or a vascular component then MRI Pelvis without and with contrast (CPT® 72197)</li> </ul>	<ul> <li>If solid component, MRI Pelvis without and with contrast (CPT® 72197) is medically necessary</li> <li>If ultrasound equivocal for Simple cyst, MRI Pelvis without and with contrast (CPT® 72197) is medically necessary</li> <li>If follow up ultrasound imaging shows changing morphology and/or a vascular component then MRI Pelvis without and with contrast (CPT® 72197) is medically necessary</li> </ul>

#### **Complex Adnexal Masses (PV-5.3)**

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- Ultrasound imaging should provide characteristics of the cyst/mass prior to consideration of advanced imaging.
- Complex cysts found on ultrasound have characteristics that include: solid areas or excrescences, and/or debris, may have greater than 3mm irregular septations, and/ or mural nodules with Doppler-detected blood flow, and/or free abdominal/pelvic fluid. Complex cysts have an O-RADS™ score of 2 or higher.
- Routine use of 3D rendering (CPT® 76376/CPT® 76377) for evaluation of complex ovarian cysts is not medically necessary unless otherwise mentioned in the table below.

#### Follow up Complex Adnexal Masses

Condition	Pre-Menopausal	Post-Menopausal
Typical hemorrhagic cyst < 10 cm (O- RADS™ 2)	<ul> <li>If initial ultrasound imaging confirms hemorrhagic cyst ≤5 cm no further imaging is medically necessary</li> <li>If initial ultrasound imaging confirms hemorrhagic cyst &gt;5 cm but &lt;10 cm, follow up with Pelvic ultrasound (CPT® 76856 or CPT® 76857) and/or TV ultrasound (CPT® 76830) in 8-12 weeks is medically necessary. Duplex (Doppler) scan (CPT® 93975 complete; CPT® 93976 limited) may be approved as an add-on to TV ultrasound (CPT® 76830).</li> <li>If follow-up imaging confirms a hemorrhagic cyst that has not completely resolved or has enlarged, MRI Pelvis without and with contrast (CPT® 72197) is medically necessary.</li> <li>If stable, follow up TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76857 or CPT® 76856) is medically necessary at 24 months from initial exam</li> </ul>	<ul> <li>Early postmenopausal (&lt;5 years) either of the following is medically necessary:</li> <li>follow-up TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76857 or CPT® 76856) in 2-3 months OR</li> <li>MRI Pelvis without and with contrast (CPT® 72197)</li> <li>Late postmenopausal (≥ 5 years) hemorrhagic cyst should not occur</li> <li>MRI Pelvis without and with contrast (CPT® 72197) is medically necessary</li> </ul>

Condition	Pre-Menopausal	Post-Menopausal
Hemorrhagic cyst ≥10cm (O- RADS™ 3)	<ul> <li>If ultrasound equivocal for Hemorrhagic cyst, MRI Pelvis without and with contrast (CPT 72197)</li> <li>If initial ultrasound imaging confirms a Typical Hemorrhagic cyst ≥10cm</li> <li>If not excised consider TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76857 or CPT® 76856) follow up within 6 months</li> <li>If stable, follow up Ultrasound can be done at 12 and 24 months from initial exam</li> <li>If solid component, MRI Pelvis without and with contrast (CPT® 72197) may be approved</li> <li>If follow up ultrasound imaging shows changing morphology and/or a vascular component then consider MRI Pelvis without and with contrast (CPT® 72197)</li> </ul>	MRI Pelvis without and with contrast (CPT® 72197) is supported

Condition	Pre-Menopausal	Post-Menopausal
Typical Endometriomas < 10cm (O- RADS™ 2)	<ul> <li>If ultrasound equivocal for Endometriomas, MRI Pelvis without and with contrast (CPT 72197)</li> <li>If initial imaging confirms a Typical Endometrioma, follow-up Pelvic ultrasound (CPT® 76856 or CPT® 76857) and/or TV ultrasound (CPT® 76830); duplex (Doppler) scan (CPT® 93975 complete; CPT® 93976 limited) may be approved as an add-on to TV ultrasound (CPT® 76830)</li> <li>If &lt;10cm and not surgically excised follow-up TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76857 or CPT® 76856) in 12 months</li> <li>If stable follow up Ultrasound can be done at 24 months from initial exam</li> <li>If follow up ultrasound imaging shows changing morphology and/or a vascular component then consider MRI Pelvis without and with contrast (CPT® 72197)</li> </ul>	If initial ultrasound imaging confirms a typical endometrioma < 10cm then either the following is medically necessary: Follow-up TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76857 or CPT® 76856) in 2-3 months OR MRI Pelvis without and with contrast (CPT® 72197)
Typical Endometriomas ≥10cm (O- RADS™ 3)	<ul> <li>If initial ultrasound imaging confirms a Typical Endometrioma ≥10cm the following is medically necessary:</li> <li>If not excised, TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76857 or CPT® 76856) follow up within 6 months</li> <li>If stable follow up Ultrasound can be done at 12 and 24 months from initial exam</li> <li>If solid component, MRI Pelvis without and with contrast (CPT® 72197) may be approved</li> <li>CPT® 72197)</li> <li>If follow up ultrasound imaging shows changing morphology and/or a vascular component then consider MRI Pelvis without and with contrast (CPT® 72197)</li> </ul>	MRI Pelvis without and with contrast (CPT® 72197) is medically necessary

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Condition	Pre-Menopausal	Post-Menopausal
Typical Dermoid < 10cm (O- RADS™ 2)	<ul> <li>If initial features are only suggestive for, or if assessment is uncertain follow-up Pelvic ultrasound (CPT® 76856 or CPT® 76857) and/or TV ultrasound (CPT® 76830) within 3 months is medically necessary</li> <li>OR</li> <li>If ultrasound equivocal for Dermoid, MRI Pelvis without and with contrast (CPT 72197) is medically necessary</li> <li>If initial ultrasound imaging confirms a Dermoid, follow-up Pelvic ultrasound (CPT® 76856 or CPT® 76857); and/or TV ultrasound (CPT® 76856) is complete; CPT® 93976 limited) may be medically necessary as an add-on to TV ultrasound (CPT® 76830).</li> <li>If ≤10 cm, may consider follow-up TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76857 or CPT® 76856) in 12 months if not surgically excised</li> <li>If stable follow up Ultrasound can be done at 24 months from initial exam</li> <li>If follow up ultrasound imaging shows changing morphology and/or a vascular component then consider MRI Pelvis without and with contrast (CPT® 72197)</li> </ul>	Same as Pre- Menopausal

Condition	Pre-Menopausal	Post-Menopausal
Typical Dermoid ≥ 10cm (O- RADS™ 3)	<ul> <li>If ultrasound equivocal for Dermoid, MRI Pelvis without and with contrast (CPT 72197)</li> <li>If initial ultrasound imaging confirms a Typical Dermoid ≥10cm</li> <li>If not excised consider TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76857 or CPT® 76856) follow up within 6 months</li> <li>If stable follow up Ultrasound can be done at 12 and 24 months from initial exam</li> <li>If solid component, MRI Pelvis without and with contrast (CPT® 72197) may be approved</li> <li>If follow up ultrasound imaging shows changing morphology and/or a vascular component then consider MRI Pelvis without and with contrast (CPT® 72197)</li> </ul>	Same as Pre- Menopausal
Typical benign extraovarian lesions Hydrosalpinges (Hydrosalpinx) or Peritoneal cysts (ORADS™ 2)	If initial imaging confirms hydrosalpinx or peritoneal cysts, follow up imaging is not medically necessary	If initial imaging confirms hydrosalpinx or peritoneal cysts, follow up imaging is not medically necessary

#### Complex and/or solid adnexal mass incompletely evaluated by ultrasound

- Generally a repeat ultrasound is medically necessary (see table above for appropriate time intervals): TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76857 or CPT® 76856)
- MRI Pelvis without and with contrast (CPT® 72197, CPT® 72195 if pregnant) one time is medically necessary as follows:
  - To follow masses when they cannot be optimally visualized by ultrasound (e.g. suboptimal sonography due to large mass or obese individual)
  - Unexplained change of appearance during ultrasound follow-up

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- Other Individual-driven indications (e.g. the application of established risk prediction models (e.g., family history of ovarian cancer), correlation with abnormal serum biomarkers, and/or pelvic symptoms)
- Differentiate the origin of pelvic masses that are not clearly of ovarian origin
- O-RADS™ score of 3 with a solid component
- O-RADS™ score of 4 or 5
- Concern for metastatic ovarian malignancy, see <u>Ovarian Cancer (ONC-21)</u> in the Oncology Imaging Guidelines

#### **Background and Supporting Information**

O-RADS™ Classification

O-RADS	
O-RADS™ 0	Incomplete Evaluation
O-RADS™ 1	Normal Ovary  • No ovarian lesion  • Physiologic cyst: follicle ≤3cm or corpus luteum typically ≤3cm
O-RADS™ 2	<ul> <li>Almost Certainly Benign</li> <li>Simple cyst less than 10 cm</li> <li>Bilocular, smooth cyst</li> <li>Unilocular, smooth, non-simple cysts (internal echos and/or incomplete septations)</li> <li>Typical benign ovarian lesions &lt;10cm (hemorrhagic cyst, dermoid cyst, endometrioma)</li> <li>Typical benign extraovarian lesions (paraovarian cyst, peritoneal inclusion cysts, hydrosalpinx)</li> </ul>
O-RADS™ 3	Low Risk  • Typical benign ovarian lesions ≥10cm  • Uni- or bilocular cyst, smooth, ≥10cm  • Unilocular cyst, irregular, any size  • Multilocular cyst, smooth, <10cm, Color Score (CS) <4  • Solid lesion, ± shadowing, smooth, any size, CS =1  • Solid lesion, shadowing, smooth, any size, CS 2-3

O-RADS	
ORADS™ 4	Intermediate Risk  • Bilocular cysts without solid component(s), Irregular, any size, any color score  • Multilocular cysts without solid component(s)
	<ul> <li>Smooth, 10 cm, CS &lt;4</li> <li>Smooth, any size, CS 4</li> <li>Irregular, any size, any CS</li> <li>Unilocular cyst with solid component(s)</li> </ul>
	<ul> <li>&lt;4 papillary projections or any solid component(s) not considered a papillary projection, any size</li> <li>BI- or multilocular cyst with solid component(s), any size, CS 1-2</li> <li>Solid lesion, non-shadowing, smooth, any size, CS 2-3</li> </ul>
ORADS™ 5	<ul> <li>High Risk</li> <li>Unilocular cyst, ≥4 papillary projections, any size, and CS</li> <li>Bi- or multilocular cyst with solid component(s), any size, CS 3-4</li> <li>Solid lesion, ± shadowing, smooth, any size, CS 4</li> <li>Solid lesion, irregular, any size, any CS</li> <li>Ascites and/or peritoneal nodules</li> </ul>

#### Pre-Menopausal – see table above

- For females of reproductive age (Pre-Menopausal), evaluation may include a pregnancy test (a quantitative hCG may be necessary if an ectopic pregnancy is suspected), CBC, serial hematocrit measurements, and appropriate cultures.
- Symptomatic individuals often require immediate interventions (antibiotics, surgery, and/or expectant management).
- Ultrasound characteristics usually suggest the diagnosis (ectopic pregnancy, functional cysts, tubo-ovarian abscess (See <u>Pelvic Inflammatory Disease (PV-7.1)</u>), hydrosalpinx, dermoid, endometrioma, hemorrhagic cyst and pedunculated fibroids (See <u>Leiomyoma/Uterine Fibroids (PV-12.1)</u>) and direct the treatment.
- An ovarian mass suspicious for metastatic disease (e.g. from breast, uterine, colorectal or gastric cancer) should be evaluated based on the appropriate Oncology Imaging Guidelines.

#### Post-Menopausal - see table above

• For post-menopausal females, most pelvic complex cysts or solid masses should be evaluated for surgical intervention and have tumor markers (i.e. CA-125) measured.

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- Some for whom the usual management of a pelvic mass would include surgery may
  be at increased risk for perioperative morbidity and mortality. In such cases, repeat
  imaging may be a safer alternative than immediate surgery, although the frequency of
  follow-up imaging has not been determined.
- An ovarian mass suspicious for metastatic disease (e.g. from breast, uterine, colorectal or gastric cancer) should be evaluated based on the appropriate Oncology Imaging Guidelines.

#### Screening for Ovarian Cancer/Suspected **Ovary Cancer (PV-5.4)**

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See Ovarian Cancer (ONC-21) in the Oncology Imaging Guidelines

#### **Evidence Discussion (PV-5)**

- Transabdominal pelvic and/or transvaginal pelvic ultrasound are widely accepted as the initial imaging modality of choice for female reproductive organs<sup>3,14</sup>. Ultrasound has high sensitivity (>90%) for adnexal pathology 14. Ultrasound also allows for realtime evaluation with color and power Doppler which can help identify vascular flow and differentiate solid components<sup>2</sup>. Additional benefits to ultrasound as a first line imaging modality include wide availability, fast access and lack of ionizing radiation exposure. MRI is accepted as an adjunct modality to ultrasound in cases where ultrasound may not fully characterize a soft tissue abnormality due to its superior signal to noise ratio 14,15,16. CT is of limited use in the evaluation of adnexal masses given its suboptimal delineation of adnexal soft tissue<sup>14</sup>.
- · Accurate diagnosis of adnexal pathology is imperative in order to limit invasive interventions for benign lesions 15 and improve preoperative triage to a gynecologic oncologist for high-risk lesions. 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 has high sensitivity for detection of malignancy (95%)<sup>4</sup>. 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%)<sup>16</sup>. For an indeterminate lesion on ultrasound or features concerning for malignancy, adjunct imaging with MRI is supported to aid in preoperative triage.

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### Endometriosis (PV-6)

Guideline

Endometriosis (PV-6.1) References (PV-6)

#### **Endometriosis (PV-6.1)**

PV.EM.0006.1.A

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- TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76856 or CPT® 76857) is medically necessary as the first line diagnostic exam for suspected endometriosis.
- MRI Pelvis without contrast (CPT® 72195) or without and with contrast (CPT® 72197) is medically necessary as follows:
  - Prior to planned surgery for suspected deep pelvic endometriosis such as rectovaginal endometriosis, deeply infiltrative bladder endometriosis, and cul-desac obliteration.
  - To characterize complex adnexal masses as endometrioma if ultrasound equivocal See <u>Complex Adnexal Masses (PV-5.3)</u>
    - If known or suspected thoracic endometriosis, see <u>Pneumothorax/Hemothorax</u> (<u>CH-19.1</u>)in the Chest Imaging Guidelines.

#### **Evidence Discussion (PV-6.1)**

- Transabdominal pelvic and/or transvaginal pelvic ultrasound (TVUS) are widely accepted as the initial imaging modality of choice for evaluation of endometriosis<sup>2,4,5,7</sup>. A meta-analysis by Hudelist et al found transvaginal ultrasound was found to have a sensitivity and specificity of 91 and 98%, respectively, with a positive predictive value of 98% and negative predictive value of 95%<sup>2</sup>. A study by Goncalves et al compared TVUS done preoperatively to diagnostic laparoscopy for deep and ovarian endometriosis<sup>7</sup>. This study found TVUS to be accurate in identifying all sites of ovarian and deep endometriosis, with significantly higher sensitivity than diagnostic laparoscopy in detecting rectosigmoid endometriosis. Additional benefits to ultrasound as a first line imaging modality include wide availability, fast access, and lack of ionizing radiation exposure.
- MRI of the pelvis can be useful for cases of suspected deep pelvic endometriosis<sup>5,3</sup>. A study by Macario et al found MRI of the pelvis prior to laparoscopy to have an overall sensitivity of 91.9% and specificity of 91.2% in the preoperative diagnosis of deep pelvic endometriosis with cul-de-sac obliteration<sup>3</sup>. MRI is also indicated for further evaluation of suspected endometrioma of the ovary if ultrasound is equivocal<sup>11,12</sup>. The American College of Radiology (ACR) Appropriateness Criteria for adnexal mass states, "When an adnexal mass is indeterminate on US, either the organ of origin is uncertain or it is unclear whether the mass is benign or malignant, then MRI with intravenous (IV) contrast (if feasible) becomes the modality of choice.<sup>12</sup>" Per the ACR Appropriateness Criteria, "MRI can readily diagnose typical endometriomas." A study by Dirrichs et al found MRI to improve sensitivity and specificity of diagnosis for indeterminate adnexal masses found with TVUS<sup>13</sup>. In this study, MRI changed the management decision in 34% of patients<sup>13</sup>.

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## Pelvic Inflammatory Disease (PID) (PV-7)

#### Guideline

Pelvic Inflammatory Disease (PV-7.1) References (PV-7)

#### Pelvic Inflammatory Disease (PV-7.1)

PV.PI.0007.1.A

v1.0.2026

- Clinical examination alone is usually sufficient for confirming the diagnosis of pelvic inflammatory disease. See <u>Pelvic Pain/Dyspareunia</u>, <u>Female (PV-11.1)</u> if other causes of pelvic pain are suspected.
- Pelvic ultrasound (CPT® 76856 or CPT® 76857) and/or TV ultrasound (CPT® 76830) is medically necessary as the initial study for imaging of suspected pelvic inflammatory disease (PID) if diagnosis is uncertain following bimanual pelvic examination and laboratory testing (such as WBC, CRP and ESR, Microscopy of the vaginal secretions, and testing for Neisseria gonorrhoeae and Chlamydia trachomatis) OR for suspected Tubo-Ovarian Abscess (TOA). Color Doppler ultrasonography (CPT® 93975 or CPT® 93976) may be added.
- CT Pelvis with contrast (CPT® 72193) or MRI Pelvis with and without contrast (CPT® 72197) is medically necessary:
  - If diagnosis is uncertain following examination, laboratory testing and ultrasound
  - Ultrasound shows extensive abscess formation and further imaging is needed for treatment planning
  - Suspected TOA with inconclusive ultrasound
- If suspected abdominal abscess see <u>Abdominal Sepsis (Suspected Abdominal Abscess) (AB-3.1)</u>in the Abdomen Imaging Guidelines.

#### **Background and Supporting Information**

PID may be clinically suspected based on findings of abdominal and/or pelvic pain, cervical or vaginal mucopurulent discharge, dyspareunia, inter-menstrual and/or post coital bleeding, fever, low back pain, nausea/vomiting, urinary frequency, cervical motion tenderness, uterine and/or adnexal tenderness on exam.

Laboratory findings may include elevated erythrocyte sedimentation rate, elevated C-reactive protein, lab documentation of cervical infection with N. gonorrheae or C. trachomatis, WBC on saline microscopy of vaginal fluid, and/or endometrial biopsy with endometritis.

#### **Evidence Discussion (PV-7.1)**

 Clinical examination and laboratory testing are appropriate in the initial diagnostic testing for suspected pelvic inflammatory disease (PID)<sup>2,7,10</sup>. Imaging studies can be helpful when further evaluation is needed and to rule out other differential diagnoses such as ovarian cysts or gastrointestinal disease<sup>2,7,10</sup>.

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- Transabdominal pelvic and/or transvaginal pelvic ultrasound are widely accepted
  as the initial imaging modality of choice for evaluation of pelvic inflammatory
  disease<sup>2,7,10,8,9</sup>. Additional benefits to ultrasound as a first line imaging modality
  include wide availability, fast access, and lack of ionizing radiation exposure. The
  addition of Power Doppler to ultrasonography has been found to increase sensitivity
  in the diagnosis of PID<sup>2,7,8,9</sup>.
- CT Pelvis or MRI Pelvis can be considered if further imaging is needed following inconclusive ultrasound for diagnosis of PID, suspected tubo-ovarian abscess, or to evaluate for the extent of PID abscess formation for treatment planning<sup>2,7,8,9,6,4</sup>.

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## Polycystic Ovary Syndrome (PV-8)

#### Guideline

Polycystic Ovary Syndrome (PCOS) (PV-8.1) References (PV-8)

## Polycystic Ovary Syndrome (PCOS) (PV-8.1)

PV.PC.0008.1.A

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- Pelvic ultrasound (CPT® 76856 or CPT® 76857) and/or TV ultrasound (CPT® 76830) is medically necessary when history, exam, and/or laboratory findings are suspicious for PCOS.
- Laboratory testing to be done prior to advanced imaging: Virilizing hormone levels (Testosterone and DHEAS). Disorders that mimic the clinical features of Polycystic ovary syndrome (PCOS) should be excluded by measuring: TSH, Prolactin, and 17-OHP (hydroxyprogesterone) levels. Others to consider based on the clinical presentation: Cortisol levels, ACTH, dexamethasone suppression testing, IGF-1, FSH, LH, estradiol.
- If elevated serum levels of androgens are found and an adrenal etiology is suspected
   see <u>Adrenal Cortical Lesions (AB-16.1)</u> in the Abdomen Imaging Guidelines.

#### **Background and Supporting Information**

- Polycystic ovary syndrome is the most common hormonal disorder among females of reproductive age, and is one of the leading causes of infertility.
- Diagnostic criteria of polycystic ovary syndrome (Two of the following three criteria are required):
  - Oligo/anovulation
  - Hyperandrogenism
    - Clinical (hirsutism or less commonly male pattern alopecia) or
    - Biochemical (raised FAI (free androgen index) or free testosterone)
  - Polycystic ovaries on ultrasound
    - Defined as an ovary containing 12 or more follicles (or 25 or more follicles using new ultrasound technology) measuring 2 to 9 mm in diameter or an ovary that has a volume of greater than 10 mL on ultrasonography. A single ovary meeting either or both of these definitions is sufficient for diagnosis of polycystic ovaries.
- Clinical Features of PCOS
  - Hirsutism and male pattern balding consistent with hyperandrogenism
  - Irregular or absent menstrual cycles
  - Subfertility or infertility
  - Psychological symptoms anxiety, depression, psychosexual dysfunction, eating disorders
  - Metabolic features obesity, dyslipidaemia, diabetes

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#### **Evidence Discussion (PV-8)**

- Transabdominal pelvic and/or transvaginal pelvic ultrasound are widely accepted as the modality of choice for evaluation of the ovaries in patients with suspected polycystic ovarian syndrome (PCOS)<sup>1,2,3,6</sup>. Ultrasound allows for real-time evaluation of the pelvic anatomy, has wide availability, fast access, and lack of ionizing radiation exposure. It also allows for follicular count which will help establish the diagnosis of PCOS<sup>1,2,3,6</sup>.
- Laboratory testing may point to other etiology of symptoms and may better direct additional imaging <sup>1,2,3,6</sup>.
- Imaging for suspected adrenal pathology is addressed in the Abdominal Section of these guidelines.

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# Initial Infertility Evaluation, Female (PV-9)

#### Guideline

Initial Infertility Evaluation, Female (PV-9.1) References (PV-9)

## Initial Infertility Evaluation, Female (PV-9.1)

PV.IE.0009.1.U

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This guideline is not intended for fertility treatment follow-up and management. See individual fertility coverage policy for imaging during active fertility treatment.

- A one-time Pelvic ultrasound (CPT<sup>®</sup> 76856 or CPT<sup>®</sup> 76857) and/or TV ultrasound (CPT<sup>®</sup> 76830) is medically necessary for initial infertility workup.
  - Repeat ultrasounds or serial ultrasounds are not medically necessary for initial infertility workup
- To evaluate for tubal patency:
  - Hysterosalpingography (HSG) (CPT<sup>®</sup> 74740) or Sonohysterosalpingography (CPT<sup>®</sup> 76831) is medically necessary
- If ultrasound is indeterminate or there is clinical suspicion for intra-cavitary lesion (such as polyp or fibroid), hydrosalpinx, uterine synechia, adenomyosis or uterine anomalies either of the following are medically necessary:
  - 3D US imaging (add-on CPT<sup>®</sup> 76376 or CPT<sup>®</sup> 76377)
  - US Color Doppler (CPT<sup>®</sup> 93975 or CPT<sup>®</sup> 93976)

#### **Background and Supporting Information**

Some payors do not provide coverage for infertility evaluation and/or treatment.

#### **Evidence Discussion (PV-9)**

- Transabdominal pelvic and/or transvaginal pelvic ultrasound are widely accepted as the initial imaging modality of choice for evaluation of the female pelvic organs <sup>1,2,5,6,8</sup>. Ultrasound allows for real-time evaluation, has wide availability, fast access, and lack of ionizing radiation exposure <sup>1</sup>. The addition of 3D ultrasound is beneficial in cases when intrauterine abnormalities are suspected <sup>5,3,4</sup>. The diagnostic accuracy of 3D ultrasound is 90% to 95% for uterine anomalies <sup>5</sup>. Adding Doppler evaluation provides information about vascularity and tissue perfusion <sup>5,7</sup>.
- Hysterosalpingography (HSG) or Sonohysterosalpingography can be utilized in assessing tubal patency. Sonohysterosalpingography is more operator dependent than HSG, however, both procedures benefit patients in that they can help avoid the more invasive laparoscopy and chromotubation, which carry the risks of surgery and anesthesia<sup>6,8</sup>.

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# Intrauterine Device (IUD) and Tubal Occlusion (PV-10)

#### Guideline

Intrauterine Device (PV-10.1)
Hysteroscopically Placed Tubal Occlusion Device (PV-10.2)
Implantable Contraceptive Devices (PV-10.3)
References (PV-10)

#### **Intrauterine Device (PV-10.1)**

PV.ID.0010.1.A

v1.0.2026

- Pelvic ultrasound (CPT® 76856 or CPT® 76857) and/or TV ultrasound (CPT® 76830) is medically necessary if:
  - Abnormal pelvic exam prior to IUD insertion, such as pelvic mass, irregularly shaped uterus, or enlarged uterus
  - Suspected IUD complication:
    - Abnormal IUD position
    - Uterine perforation
    - Severe pain
    - Excessive bleeding
    - Suspected infection

#### "Lost" IUD inability to palpate IUD string on pelvic exam, and/or see IUD on speculum exam:

- If unable to palpate, see or retrieve IUD string on pelvic exam and/or speculum exam an attempt to retrieve IUD strings with cytobrush or instrumentation of the cervix should be undertaken prior to imaging.:
  - TV ultrasound CPT® 76830 and/or Pelvic ultrasound (CPT® 76856 or CPT® 76857); with or without 3-D Rendering (CPT® 76377 or CPT® 76376) is medically necessary:
    - If TV and/or Pelvic ultrasound is negative or non-diagnostic, plain x-ray should be performed if pregnancy test is negative
      - If IUD is not visualized on x-ray a diagnosis of expulsion can be made
    - CT Pelvis without contrast (CPT® 72192) or CT Abdomen and Pelvis without contrast (CPT® 74176) or MRI Pelvis without contrast (CPT® 72195) is medically necessary when both ultrasound and plain x-ray are equivocal or nondiagnostic as it may be useful to delineate IUD position and relationship to other abdominal organs.
- If pregnancy test is positive:
  - The use of gynecology CPT codes for pregnant females is not supported. Therefore, transvaginal ultrasound (CPT® 76830) and pelvic ultrasound (CPT® 76856 or CPT® 76857) are not medically necessary for those with a positive pregnancy test or known pregnancy. If a pregnancy test is positive, then obstetrical CPT codes are indicated. (General Guidelines (PV-1.0)).

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## Hysteroscopically Placed Tubal Occlusion Device (PV-10.2)

PV.ID.0010.2.A

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- TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76856 or CPT® 76857) is medically necessary if:
  - Suspected complication of hysteroscopically placed tubal occlusion device:
    - Abnormal tubal occlusion device position
    - Uterine perforation
    - Severe pain
    - Excessive bleeding

## Implantable Contraceptive Devices (PV-10.3)

PV.ID.0010.3.A

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- If implant is unable to be palpated
  - If implant is radiopaque (contains barium sulphate)
    - Initial imaging should include either Ultrasound or X-ray of arm
    - If thoracic implant migration is suspected Chest X-ray should be considered
    - If Chest X-ray is equivocal CT Chest without or with contrast (CPT® 71250 or CPT® 71260) or CTA Chest (CPT® 71275) is medically necessary
  - If implant is radiolucent
    - Initial imaging should include Ultrasound of the arm
    - MRI Upper Extremity without contrast (CPT® 73218) is medically necessary if ultrasound is equivocal
    - If thoracic implant migration is suspected MRI Chest without or without and with contrast (CPT® 71550 or CPT® 71552) is medically necessary

#### **Background and Supporting Information**

- As of 2019, neither the Essure nor the Adiana tubal occlusion device is in production.
- Currently the only implant available in the United States is an etonogester containing implant. The original version of this implant (Implanon) was released in 2001. This was replaced by an updated implant in 2011 (Nexplanon) which contains barium sulphate, making it radiopaque and easily visualized on X-ray.
- A rare complication of the implant is distant vascular migration to the pulmonary vasculature.

#### **Evidence Discussion (PV-10)**

- Transabdominal and transvaginal ultrasounds are the initial imaging methods for locating a malpositioned IUD 12,14,11,5,2,3. Ultrasound has the benefits of being widely available, accurate, and free from exposure to ionizing radiation. The addition of 3D image processing to ultrasound is advantageous as it allows for the visualization of the complete IUD, including the shaft and arms, and demonstrates its relationship to the endometrial cavity 8,2,3.
- In cases where the ultrasound is non-diagnostic and the pregnancy test is negative, an X-ray should be performed. X-rays are useful as IUDs are radiopaque; if the IUD is not visualized on an X-ray, a diagnosis of expulsion can be made<sup>11</sup>.

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<ul> <li>If both ultrasound and X-ray results are equivocal, CT or MRI is delineate the IUD's position and its relationship to other abdon</li> </ul>	may be useful to ninal organs <sup>1,6</sup> .

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# Pelvic Pain/Dyspareunia, Female (PV-11)

#### Guideline

Pelvic Pain/Dyspareunia, Female (PV-11.1) References (PV-11)

## Pelvic Pain/Dyspareunia, Female (PV-11.1)

PV.PD.0011.1.U

v1.0.2026

- This guideline is intended for the workup of pelvic pain in relation to the female pelvic organs
  - If there is clinical concern for a non-gynecological cause of pelvic pain please see the most applicable condition-specific guideline (e.g., General Abdomen, General, General Peripheral Vascular Disease, General Nerve and Neuromuscular Disorder Imaging, etc.)
  - History, physical examination, and laboratory data can guide subsequent workup in individuals presenting with pelvic pain.
    - A pregnancy test should be performed in premenopausal females
  - Ultrasound is the initial work up for pelvic pain suspected to originate from the female pelvic organs
    - Premenopausal pelvic pain and the pregnancy test is positive,
      - See the applicable obstetrical imaging policy
    - Premenopausal pelvic pain and the pregnancy test is negative or the patient is postmenopausal
      - Ultrasound transvaginal (CPT® 76830) and/or pelvic (CPT® 76856 or CPT® 76857)
      - Duplex Doppler (CPT® 93975 or CPT® 93976) is medically necessary if there is an ovarian mass and/or suspicion of ovarian torsion on the initial ultrasound.
      - Duplex Doppler (CPT® 93975 or CPT® 93976) is medically necessary for chronic pelvic pain (pelvic pain for 6 months or greater)
  - If ultrasound is indicative of pelvic organ disease, etc.)
    - Further imaging as per appropriate section of guidelines (i.e.-ovarian mass/ torsion <u>Adnexal Mass/Ovarian Cysts (PV</u>-5), PID <u>Pelvic Inflammatory</u> <u>Disease (PV-7.1)</u>, etc.)
  - If initial ultrasound is normal
    - Further evaluation depending on the clinical suspicion may include urological work-up, gastroenterology work-up, laparoscopic evaluation(s)

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- If the initial ultrasound is equivocal for unexplained chronic pelvic pain (pelvic pain for 6 months or greater) and/or above evaluations are non-diagnostic the following is medically necessary:
  - CT Pelvis with contrast (CPT® 72193) OR
  - MRI Pelvis without contrast or with and without contrast (CPT® 72195 or CPT® 72197)
- Dysmenorrhea
  - Primary Dysmenorrhea
    - Empiric treatment with Nonsteroidal Anti-inflammatories, Hormonal Therapies or non-pharmacologic strategies
    - If failure of empiric treatment Secondary Dysmenorrhea should be suspected
  - Secondary Dysmenorrhea
    - Initial evaluation is with Ultrasound transvaginal (CPT® 76830) and/or pelvic (CPT® 76856 or CPT® 76857)
    - Additional work up depends on the pelvic pathology suspected
    - For suspected Endometriosis (PV-6)
    - For suspected Adenomyosis (PV-4)
    - For suspected <u>Fibroids</u> (PV-12)
- Evaluation for Pelvic Adhesive Disease
  - Initial imaging is an Abdominal (CPT® 76700 or CPT® 76705) and/or Pelvic Ultrasound (CPT® 76856 or CPT® 76857) to complete assessment for surgical planning
    - If ultrasound is inconclusive then MRI Pelvis without contrast or with and without contrast (CPT® 72195 or CPT® 72197) is medically necessary for surgical planning
- Persistent Genital Arousal Disorder/Genito-Pelvic Dysesthesia (PGAD/GPD)
  - Work-up should include detailed history, physical exam, and appropriate laboratory exams and neurogenital testing
  - Further work-up is dependent on the suspected etiology
    - For Urethral Diverticula See <u>Urethral Diverticula (PV-13.2)</u>
    - For pelvic floor dysfunction See <u>Urinary Incontinence/Pelvis Prolapse/</u>
       <u>Fecal Incontinence (PV-22)</u>
    - For Tarlov Cyst See <u>Miscellaneous Spinal Lesions (SP 2.8)</u>
    - For Pudendal Neuropathy See
    - For Pelvic Congestion Syndrome See <u>Pelvic Congestion Syndrome</u> (PVD-13.4)

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- Work-up of interstitial cystitis/bladder pain syndrome (IC/BPS) should include history, physical exam, laboratory exam (urinalysis and urine culture), cystoscopy, and measurement of post void residual urine by bladder catheterization.
  - Pelvic ultrasound (CPT® 76856 or CPT® 76857) and/or TV ultrasound (CPT® 76830) is then medically necessary.
    - CT Pelvis with contrast (CPT® 72193) is medically necessary if ultrasound is equivocal for complicated interstitial cystitis/bladder pain syndrome.
- Proctalgia Syndromes
  - Prior to advanced imaging, the evaluation of rectal/perineal pain should include:
    - Digital rectal examination (assess for mass, fissures, hemorrhoids, etc.)
    - Pelvic examination in females to exclude PID
    - Recent flexible sigmoidoscopy or colonoscopy subsequent to the start of reported symptoms to exclude inflammatory conditions or malignancy.
    - Endoanal ultrasound (CPT® 76872), MRI Pelvis with and without contrast (CPT® 72197), or CT Pelvis with contrast (CPT® 72193) are medically necessary after the above studies have been performed or if laboratory or clinical information suggest infection, abscess, or inflammation
- MRI (MRI Pelvis without contrast CPT® 72195) for Defecography is considered investigational/experimental by UHC.

#### **Background and Supporting Information**

- Dysmenorrhea is pain with the menstrual cycle. It can be divided into primary dysmenorrhea (pain in the absence of pelvic pathology) and secondary dysmenorrhea (pain due to pelvic pathology or recognized medical condition).
- Multiple meta-analyses have been performed regarding the detection of intraabdominal adhesions by various imaging modalities. Limperg et al found that ultrasound has a sensitivity of 95.9%, specificity of 93.1%, a PPV of 60.4% and a NPV of 99.2% for the identification for assessment of periumbilical bowel adhesion. In addition, Gerner-Rasmussen found an overall accuracy for detecting intra-abdominal adhesions of 76-100% for ultrasound, 79-90% for MRI and 66% for CT. Ultrasound has the benefit of being widely available and lacks exposure to contrast agents. MRI is able to visualize adhesions between viscera, but has a higher false positive rate and over diagnoses adhesions.
- Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS) has an unpleasant sensation (pain, pressure, discomfort), perceived to be related to the urinary bladder. It is associated with lower urinary tract symptoms of more than six weeks duration, in the absence of infection or other identifiable causes.
- Proctalgia syndromes are characterized by recurrent episodes of rectal/perineal pain, and may be due to sustained contractions of the pelvic floor musculature.

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#### **Evidence Discussion (PV-11)**

- Transabdominal pelvic and/or transvaginal pelvic ultrasound are widely accepted as the initial imaging modality of choice for pelvic pain of gynecologic origin 3,9,10,11 Ultrasound also allows for real-time evaluation with color and power Doppler which can help identify vascular flow and distinguish fluid and cysts from soft tissue 9,10,11 Additional benefits to ultrasound as a first line imaging modality include wide availability, fast access, and lack of ionizing radiation exposure.
- MRI is accepted as an adjunct modality to ultrasound in cases where ultrasound may not fully characterize a soft tissue abnormality due to its superior signal to noise ratio<sup>9,10,11</sup>
  - CT of the pelvis may demonstrate engorged veins, pelvic fulid, peritoneal thickening, hydrosalpinx or pyosalpinx and tubo-ovarian abscess<sup>9,10</sup>.
- MRI pelvis, CT pelvis or endoanal ultrasound are appropriate for the evaluation of proctalgia after digital rectal examination, pelvic examination in females and recent endoscopy to exclude inflammatory conditions or malignancy<sup>4</sup>.
- Often, the history, physical examination, and laboratory data can guide subsequent workup in individuals presenting with pelvic pain. If initial ultrasound is normal, further evaluation may include urological work-up, gastroenterology work-up, or laparoscopic evaluation(s)'.
  - The differential diagnosis for chronic pelvic pain is extensive. Determining the etiology of pelvic pain is important to plan treatment<sup>5,6,7</sup>.

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# Leiomyoma/Uterine Fibroids and other **Uterine Masses (PV-12)**

#### Guideline

Suspected Uterine Mass (PV-12.0) Leiomyoma/Uterine Fibroids (PV-12.1) Endometrial Polyp (PV-12.2) Asymptomatic Thickened Endometrium (PV-12.3) References (PV-12)

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# **Suspected Uterine Mass (PV-12.0)**

PV.UF.0012.1.A

- · A potential mass found on exam and/or found incidentally on other imaging
  - Transvaginal (TV) ultrasound imaging (CPT® 76830) is the medically necessary initial study
    - Pelvic ultrasound (CPT® 76856 or CPT® 76857) is medically necessary if requested as a complimentary study to the TV ultrasound
  - Further imaging as per appropriate section of guidelines (i.e., ovarian mass/torsion Adnexal Mass/Ovarian Cysts (PV-5), Adenomyosis (PV-4.1), etc.)

# Leiomyoma/Uterine Fibroids (PV-12.1)

PV.UF.0012.1.A

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Leiomyomata are also known as "fibroids."

- Pelvic ultrasound (CPT® 76856 or CPT® 76857) and/or TV ultrasound (CPT® 76830) are medically necessary for any of the following:
  - Suspected leiomyoma with symptoms of pelvic pain, suspected ureteral obstruction secondary to inability to void urine, pelvic pressure and/or abnormal uterine bleeding and/or an enlarged uterus found on physical exam with a negative pregnancy test (if pre-menopausal).
  - Pre-operative prior to myomectomy
  - Recurrent symptoms such as abnormal bleeding, pain, or pelvic pressure
  - 3-D Rendering (CPT® 76377 or CPT® 76376) and/or Duplex (Doppler) scan (CPT® 93975 complete; CPT® 93976 limited) if ultrasound is equivocal and intracavitary lesion is suspected, or for surgical planning for myomectomy
  - There is no current evidence to support 3-D Rendering (CPT® 76377 or CPT® 76376) for planning for uterine artery embolization.
- MRI Pelvis and/or Abdomen to determine surgical approach for hysterectomy is not medically necessary.
- MRI Pelvis without and with contrast (CPT® 72197), or without contrast (CPT® 72195) in the evaluation of leiomyomas is medically necessary for the following:
  - Guide the treatment of leiomyoma/fibroid in an enlarged uterus with multiple leiomyoma/fibroid following indeterminate ultrasound when myomectomy is planned.
  - Equivocal sonohysterography or panoramic hysteroscopy with suspected submucous leiomyoma and imaging is needed to plan for myomectomy
  - Leiomyoma necrosis is suspected
  - Guide the treatment of leiomyoma/fibroid in an enlarged uterus with multiple leiomyoma/fibroid following indeterminate ultrasound when Radiofrequency Ablation of Leiomyomas is planned
  - Uterine artery embolization is being considered
    - If MRI is equivocal, MRA Pelvis (CPT® 72198) or CTA Pelvis (CPT® 72191) if requested by or in consultation with the interventional radiologist planning the uterine artery embolization
    - There is no evidence to support interval MRI after embolization unless persistent or recurrent symptoms

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- The vascular embolization code (CPT® 37243) is inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention.
  - Additional advanced imaging codes are not medically necessary during the procedure to complete the intervention.
- If malignancy is suspected, See Oncology Imaging Guidelines.
  - MRI Pelvis with and without (CPT® 72197) for suspected leiomyosarcoma is medically necessary if one or more of the following ultrasound features AND symptoms are present;
    - Ultrasound features suggestive of leiomyosarcoma are:
      - Large sized (greater than 8 cm)
      - Irregular borders
      - Areas of cystic change or necrosis
      - Increase in central and peripheral vascularity
      - Rapid change in size
    - Symptoms suggestive of leiomyosarcoma would include postmenopausal woman with an new or rapidly enlarging myometrial mass or rapid growth of a uterine mass in a premenopausal patient (increase of 6 weeks gestation size within 1 year)
- CT is not medically necessary for evaluating female pelvic anatomy due to its limited soft tissue contrast resolution

#### **Evidence Discussion (PV-12)**

- Transabdominal pelvic and/or transvaginal pelvic ultrasound are widely accepted as the initial imaging modality of choice for uterine fibroids<sup>1,2</sup>. Ultrasound also allows for real-time evaluation with color and power Doppler which can help identify vascular flow and distinguish fluid and cysts from soft tissue. 3-D rendering is useful for further evaluation of intracavitary lesions and for surgical planning for myomectomy<sup>3</sup>. Additional benefits to ultrasound as a first line imaging modality include wide availability, fast access, and lack of ionizing radiation exposure.
- MRI is accepted as an adjunct modality to ultrasound in cases where ultrasound may not fully characterize a soft tissue abnormality due to its superior signal to noise ratio. MRI can be useful for surgical planning for myomectomy, determining degeneration or necrosis of fibroids, and to plan uterine artery embolization or radiofrequency ablation<sup>4,5,7,9</sup>
- MRI may be considered for suspected leiomyosarcoma in cases where ultrasound features and symptoms are suggestive of this diagnosis<sup>8</sup>. The reported prevalence of unsuspected sarcoma at surgery for symptomatic leiomyoma ranges widely, from 0.01% (one in 10 000) to 0.28% (one in 352)8.

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- MRI offers the highest accuracy for characterization of uterine masses before intervention due to improved soft-tissue contrast, larger field of view, diffusion sequences, and multiplanar sequences. For procedural planning, MRI offers better localization of fibroid position in the uterus and can be used to assess viability and arterial supply of fibroids. In the context of preprocedural planning, MRI features have been evaluated for performance in separating leiomyosarcoma from leiomyomas or atypical leiomyomas. MRI features noted in multiple studies as associated with leiomyosarcoma include the following features: intermediate to high signal intensity of the mass at T2-weighted imaging, irregular margins of the uterine mass with the adjacent myometrium, and high signal intensity at high—b value diffusion-weighted imaging and corresponding low signal intensity on apparent diffusion coefficient maps<sup>8</sup>.
- MRA or CTA may be used to determine vascular flow to uterine fibroids for embolization planning in cases where MRI is insufficient. Knowledge of the vascular supply for fibroids is crucial for successful embolization of target arteries<sup>11</sup>.
- CT is of limited use in the evaluation of pelvic anatomy due to its limited soft tissue contrast resolution 10.

# **Endometrial Polyp (PV-12.2)**

PV.UF.0012.1.A

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- Transvaginal (TV) ultrasound imaging (CPT® 76830) is the medically necessary initial study
  - Pelvic ultrasound (CPT® 76856 or CPT® 76857) is medically necessary if requested as a complimentary study to the TV ultrasound
  - 3-D Rendering (CPT® 76377 or CPT® 76376) is medically necessary for further delineation of the intracavitary lesion
- Hysteroscopy remains the gold standard for diagnosis and treatment of endometrial polyps
  - · Allows for direct visualization, histologic diagnosis and concurrent treatment of the
  - If biopsy confirms a malignancy, then see the appropriate oncology guideline

# Asymptomatic Thickened Endometrium (PV-12.3)

PV.UF.0012.1.A

- Thickened endometrium (>4mm) incidentally discovered in a postmenopausal individual without bleeding
  - Need not routinely trigger evaluation, but individualized assessment, including endometrial sampling, based on patients risk factors is medically necessary
    - If biopsy confirms a malignancy, then see the appropriate oncology guideline
    - Advanced imaging is not medically necessary for Endometrial Intraepithelial Neoplasia or Atypical Endometrial Hyperplasia (EIN-AEH) as imaging has not been found to improve outcomes for this condition.

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# Periurethral Cysts, Urethral Diverticula, and Vaginal Masses (PV-13)

#### Guideline

Periurethral cysts, Skene duct cyst, Bartholin's gland cysts and Gartner's duct cyst (PV-13.1)

Urethral Diverticula (PV-13.2)

Vaginal Masses (PV-13.3)

References (PV-13)

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# Periurethral cysts, Skene duct cyst, Bartholin's gland cysts and Gartner's duct cyst (PV-13.1)

PV.UD.0013.1.A

- Initial evaluation includes any of the following:
  - Pelvic ultrasound (CPT® 76856 or CPT® 76857) and/or Transvaginal ultrasound (CPT® 76830) and/or Transperineal ultrasound (CPT® 76872) is medically necessary
    - MRI Pelvis without and with contrast (CPT® 72197) is medically necessary for surgical planning when ultrasound equivocal

# **Urethral Diverticula (PV-13.2)**

PV.UD.0013.2.A

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- Pelvic ultrasound (CPT® 76856 or CPT® 76857) and/or Transvaginal ultrasound (CPT® 76830) and/or Transperineal ultrasound (CPT® 76872) are medically appropriate for initial evaluation but are not required prior to advanced imaging.
- Urethrography or CT Urethrography (CT Pelvis without and with contrast CPT® 72194 or CT Pelvis with contrast CPT® 72193) is medically necessary to evaluate any urethral abnormalities.
- MRI Pelvis without and with contrast (CPT® 72197) is medically necessary for surgical planning

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# Vaginal Masses (PV-13.3)

PV.UD.0013.3.A

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- Pelvic ultrasound (CPT® 76856 or CPT® 76857) and/or Transvaginal ultrasound (CPT® 76830) and/or Transperineal ultrasound (CPT® 76872) is medically necessary for initial evaluation
- MRI Pelvis without and with contrast (CPT® 72197) is medically necessary for surgical planning

#### **Background and Supporting Information**

Symptomatic infection of congenital periurethral glands can result in urethral diverticula. Symptoms include pain, urinary urgency, frequency of urination, recurrent urinary tract infection, dribbling after urination, or incontinence.

#### **Evidence Discussion (PV-13)**

- Transabdominal, transvaginal and transperineal ultrasound are often utilized as initial imaging for female pelvic anatomy<sup>5,6,10,11</sup>. Ultrasound has the benefit of being widely available, accurate and does not have exposure to ionizing radiation. MRI is useful in cases of equivocal ultrasound imaging or for surgical planning<sup>5,6,11</sup>.
- Multiple modalities can be used for the detection of urethral diverticula. Transperineal and transvaginal ultrasound can be utilized in detecting urethral diverticula. Ultrasound has the advantage of being readily available, does not require catheterization and lacks exposure to ionizing radiation. However ultrasound is operator dependent and the reported sensitivity for detection of urethral diverticula ranges from <50 to 100%<sup>4</sup>. Urethrography can also be used to detect urethral diverticula with a sensitivity of 67-95% but carries the risk of radiation exposure<sup>4</sup>. MRI has excellent soft tissue resolution and has a reported sensitivity of 100% for urethral diverticula<sup>2</sup>.

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# Congenital (Mullerian) Uterine and Vaginal Anomalies (PV-14)

#### Guideline

Uterine Anomalies (PV-14.1) Vaginal Anomalies (PV-14.2) References (PV-14)

## **Uterine Anomalies (PV-14.1)**

PV.UA.0014.1.A

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- This guideline is intended for congenital uterine anomalies.
- Pelvic ultrasound (CPT® 76856 or CPT® 76857) and/or TV ultrasound (CPT® 76830) is medically necessary for initial evaluation. 3-D Rendering (CPT® 76377 or CPT® 76376) may be an add-on if uterine anomaly is suspected on ultrasound.
- If ultrasound is indeterminate:
  - Sonohysterosalpingography (CPT® 76831) is medically necessary
- Retroperitoneal ultrasound (CPT® 76770 or CPT® 76775) is medically necessary to evaluate for possible coexisting renal anomalies if a complex uterine anomaly is present.
  - MRI Abdomen without contrast or without and with contrast (CPT® 74181 or CPT® 74183) or CT urography (CT Abdomen and Pelvis without and with contrast CPT® 74178) is medically necessary for indeterminate renal anomaly on ultrasound.
- An arcuate uterus is considered a normal variant. Therefore, advanced imaging of a known arcuate uterus is not medically necessary.
- MRI Pelvis without and with contrast (CPT® 72197) is medically necessary when:
  - Ultrasound is indeterminate for a complex uterine anomaly, or
  - Requested for surgical planning of previously diagnosed uterine anomaly
    - If ultrasound confirms uterine septum, advanced imaging is not indicated for surgical planning

#### **Background and Supporting Information**

Mullerian anomalies are complex structural anomalies deriving from errors in the embryonic development of the mullerian duct. These may include uterine remnant or agenesis, cervical agenesis, unicornate utereus, bicornuate uterus, uterine didelphys, vaginal septum and/or other complex anomalies. Uterine septum is not a complex uterine anomaly.

# Vaginal Anomalies (PV-14.2)

PV.UA.0014.2.A

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- This guideline is intended for congenital vaginal anomalies.
- Pelvic ultrasound (CPT® 76856 or CPT® 76857) and/or TV ultrasound (CPT® 76830) and/or Transperineal ultrasound (CPT® 76872) and/or Translabial ultrasound (CPT® 76857) are medically necessary for initial evaluation. 3-D Rendering (CPT® 76377 or CPT® 76376) is medically necessary as an add-on if vaginal anomaly is suspected on ultrasound.
- MRI Pelvis without and with contrast (CPT® 72197) is medically necessary when:
  - Ultrasound is indeterminate for a complex vaginal anomaly, or
  - Requested for surgical planning of previously diagnosed vaginal anomaly

#### **Background and Supporting Information**

Mullerian anomalies are complex structural anomalies deriving from errors in the
embryonic development of the mullerian duct. These may include uterine remnant or
agenesis, cervical agenesis, unicornate utereus, bicornuate uterus, uterine didelphys,
vaginal septum and/or other complex anomalies. Uterine septum is not a complex
uterine anomaly.

#### **Evidence Discussion (PV-14)**

- Transabdominal and transvaginal ultrasound remain the preferred initial imaging
  for female pelvic anatomy<sup>1</sup>. Ultrasound has the benefit of being widely available,
  accurate and does not have exposure to ionizing radiation, making it an excellent
  first line modality for the evaluation of Müllerian anomalies. With the addition of 3D
  imaging, ultrasound has a reported sensitivity as high as 100% for the detection of
  uterine anomalies<sup>2</sup>. MRI is also highly sensitive for the detection of uterine anomalies
  and is useful in cases of equivocal ultrasound imaging or for surgical planning of
  known complex malformations<sup>2</sup>.
- For detection of congenital anomalies of the kidney and upper urinary tract ultrasound is usually the first line imaging modality because of its wide availability, low cost and lack of ionizing radiation<sup>6,7</sup>. CT or MRI can be utilized for further delineation of the renal anatomy in cases where ultrasound is inconclusive.

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# Fetal MRI and Other Pregnancy Imaging (PV-15)

#### Guideline

Fetal MRI (PV-15.1)

Placenta Accreta/Placenta Accreta Spectrum/Placenta Percreta (PV-15.2)

C-section, Cornual or Interstitial Ectopic Pregnancy (PV-15.3)

Pelvimetry (PV-15.4)

Abnormal Non-Invasive Prenatal Testing (NIPT) and Maternal Malignancy (PV-15.5)

References (PV-15)

# Fetal MRI (PV-15.1)

PV.MR.0015.1.A

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#### **CPT® Code Guidance**

- Fetal MRI (CPT® 74712) [plus CPT® 74713 for each additional fetus]
- Do not report CPT® 74712 and CPT® 74713 in conjunction with CPT® 72195, CPT® 72196, CPT® 72197
- If only placenta or maternal pelvis is imaged without fetal imaging, use MRI Pelvis (CPT® 72195)

#### Indications for Fetal MRI

- Fetal MRI (CPT® 74712) [plus CPT® 74713 for each additional fetus] optimally
  performed after 18 to 22 weeks gestation, is medically necessary for assessment of
  known or suspected fetal abnormalities for counseling, surgical, or delivery planning.
  - There are cases when surgical planning may necessitate imaging earlier than 18 weeks. For those cases where surgery is to be performed prior to 18 weeks and they otherwise meet indications for imaging per this criteria, Fetal MRI may be approved.
- 3D-4D (CPT® 76376 or CPT® 76377) rendering can be added for surgical planning with diagnosis of complex CHD in the fetus or for surgical planning of other complex fetal malformations
- Repeat fetal MRI (CPT® 74712) [plus CPT® 74713 for each additional fetus] is medically necessary later in pregnancy for:
  - Delivery or perinatal surgical planning
- Fetal MRI indications include but may not be limited to the following:
  - Brain
    - Congenital anomalies
      - Ventriculomegaly
      - Agenesis of the corpus callosum
      - Abnormalities of the cavum septum pellucidum
      - Holoprosencephaly
      - Posterior fossa anomalies
      - Malformations of cerebral cortical development
      - Microcephaly
      - Solid or cystic masses
      - Cephalocele

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- Screening fetuses with a family risk for brain anomalies
  - Tuberous sclerosis
  - Corpus callosal dysgenesis
  - Malformations of cerebral cortical development
- Vascular abnormalities
  - Vascular malformations
  - Hydranencephaly
  - Intra-uterine cerebrovascular accident (CVA)
- Spine
  - Congenital anomalies
    - Neural tube defects
    - Sacrococcygeal teratomas
    - Caudal regression/sacral agenesis
    - Syringomyelia
    - Vertebral anomalies
- Skull, face, and neck
  - Masses of the face and neck
    - Vascular or lymphatic malformations
    - Hemangiomas
    - Goiter
    - Teratomas
    - Facial clefts
  - Airway obstruction
    - Conditions that may impact parental counseling, prenatal management, delivery planning, and postnatal therapy
- Thorax
  - Masses
    - Congenital pulmonary airway malformations (congenital cystic adenomatoid malformation; sequestration, and congenital lobar emphysema);
    - Congenital diaphragmatic hernia
    - Effusion
    - Mediastinal masses
    - Assessment for esophageal atresia
  - Volumetric assessment of lung
    - Cases at risk for pulmonary hypoplasia secondary to oligohydramnios, chest mass, or skeletal dysplasias
- Abdomen, retroperitoneal and pelvis
  - Bowel anomalies such as anorectal malformations, or complex bowel obstructions such as with megacystis microcolon hypoperistalsis syndrome

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- Abdominal wall defect
- Mass
  - Abdominal-pelvic cyst
  - Tumors (e.g. hemangiomas, neuroblastomas, sacrococcygeal teratomas, and suprarenal or renal masses)
- Complex genitourinary anomalies (e.g. cloaca, prune belly syndrome)
- Congenital Heart Disease (CHD)
- Skeletal dysplasia
- Multiple malformations
- Complications of monochorionic twins/TTTS (e.g. Laser treatment of twins, demise of one twin, conjoined twins)
- Any suspected fetal anomaly associated with severe oligohydramnios or anhydramnios.

# Placenta Accreta/Placenta Accreta Spectrum/Placenta Percreta (PV-15.2)

PV.MR.0015.2.A

- Obstetrical Ultrasound is medically necessary as the initial imaging modality, Color Doppler CPT® 93975 Duplex scan (complete) or CPT® 93976 Duplex scan (limited) is medically necessary as an add-on to evaluate vascularity for suspected or confirmed placenta accreta spectrum
- MRI Pelvis without contrast (CPT® 72195) is medically necessary if the ultrasound is indeterminate or advanced imaging is needed for surgical planning.
- MRI Pelvis without contrast (CPT® 72195) is medically necessary if only placenta or maternal pelvis is imaged without fetal imaging

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# C-section, Cornual or Interstitial Ectopic Pregnancy (PV-15.3)

PV.MR.0015.3.A

- If a cornual (interstitial) ectopic or C-section scar ectopic pregnancy is suspected on ultrasound the following are medically necessary:
  - $^\circ~$  3D rendering (CPT® 76376 or CPT® 76377), and/or Color Doppler (CPT® 93976) is medically necessary with ultrasound
  - MRI Pelvis without contrast (CPT® 72195) is medically necessary if ultrasound is inconclusive.

# Pelvimetry (PV-15.4)

PV.MR.0015.4.A

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Pelvimetry (CT or MRI Pelvimetry) lacks sufficient evidence to be clinically useful.
 Current recommendations are that further randomized control studies be performed before it is adapted into routine clinical practice.

#### **Evidence Discussion (PV-15)**

- Transabdominal and transvaginal obstetric ultrasound remain the preferred initial imaging for fetal evaluation of the fetus and maternal pelvic anatomy<sup>1</sup>. Ultrasound has the benefit of being widely available and does not have exposure to ionizing radiation.
- Fetal MRI has emerged as an adjunct imaging to fetal ultrasound in cases where the initial ultrasound is unclear or additional information is needed for surgical or delivery planning. It has the benefits of not being limited by maternal body habitus, fetal position, ossification of fetal skull/bones, or oligohydramnios<sup>1</sup>.
- There is much uncertainty surrounding the use of gadolinium in pregnancy.
  Gadolinium is water-soluble and can cross the placenta, reaching the amniotic fluid
  and fetal circulation. While the risk of fetal effects of gadolinium remains uncertain,
  it has been shown to be teratogenic in animal studies. Given these possible fetal
  risks, the use of gadolinium in pregnancy should be limited. Its use should only be in
  situations where the benefits clearly outweigh the risks<sup>8</sup>.
- MRI can be used as an adjunct to ultrasound if there is suspicion for abnormal placentation. Sensitivity and specificity for placental invasion is comparable between ultrasound and MRI (sensitivity of 88% and sensitivity of 86% for ultrasound and 93% and 94% for MRI)<sup>14</sup>. MRI has also been associated with both false positive and false negative diagnoses. Hence, a stepwise approach to evaluation, starting with ultrasound, then followed by the use of MRI for equivocal or nondiagnostic ultrasound is supported.
- Ectopic pregnancy is the leading cause of maternal mortality in the first trimester<sup>9</sup>. Ultrasound remains the initial imaging modality for ectopic pregnancy, but MRI may add additional information, especially in cases of rare implantation-site ectopic pregnancy (e.g. Cesarean Section scar ectopic). MRI is indicated in cases where the ultrasound is nondiagnostic<sup>9</sup>.
- There is currently insufficient evidence to support the use of imaging pelvimetry (x-ray, CT or MRI) in delivery planning <sup>11</sup>.

# Abnormal Non-Invasive Prenatal Testing (NIPT) and Maternal Malignancy (PV-15.5)

PV.MR.0015.4.A

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- Non-invasive Prenatal Testing (NIPT) is a common screening method to assess the
  risk of fetal aneuploidy in the antenatal period. Cell-free DNA (cfDNA) of placental
  origin circulating in the maternal blood is tested, typically by chromosome microarray
  analysis, for certain aneuploidies. The presence of genomic anomalies originating
  from a maternal source can confound these results and have also been linked to
  occult maternal malignancy.
- · When found, maternally derived anomalies merit further work up.
  - Complete work up to rule out fetal source of anomalous results should be performed.
    - This would include further testing such as detailed fetal anatomy scan, amniocentesis or chorionic villus sampling (CVS) if applicable.
  - A targeted maternal work-up should be performed.
    - Complete history, physical and appropriate lab work up (i.e. CBC, peripheral smear, LDH, Liver and renal function testing, appropriate tumor markers) should be performed to better elucidate possible malignant source.
      - If clinical work up reveals a suspected source, targeted imaging depending on suspected source (i.e. mammogram, chest x-ray, liver ultrasound) should be undertaken
      - If clinical work up does not reveal potential source
        - Whole Body MRI (CPT® 76498) is medically necessary

#### **Background and Supporting Information**

Studies have show that the most common cancers found among those with abnormal NIPT were of hematologic origin, followed by breast and colon cancers.

Some tumor markers are less reliable in pregnancy. CA 125, CA 15.3, AFP and SCC Ag can be elevated in normal pregnancy. However, CA19-9, LDH, AMH, CEA and HE-4 are not commonly elevated in pregnancy. These tumor markers can aid in focusing clinical work up. NIPT is typically performed in the first and the early second trimesters. This is prior to physiologic elevation of inhibin B in the third trimester and development of

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hypertensive abnormalities of pregnancy (which can increase LDH), so these markers may be considered in early pregnancy.

#### **Evidence Discussion (PV 15.5)**

No prospective large-scale studies have evaluated NIPT and incidental detection on maternal malignancy, hence the specificity and sensitivity of this testing remains unknown. However, a series of retrospective studies report a positive predictive value of NIPT for detection of occult maternal malignancy of over 50%. There are currently no evidence-based guidelines by which to classify a NIPT result as suspicious for malignancy <sup>1,2,3,4,5</sup>.

If initial work up determines a maternal source of the abnormal NIPT, targeted maternal work up is merited. If targeted work up fails to reveal possible source of abnormal NIPT then additional screening is merited<sup>5,6</sup>. Whole body MRI is preferred in pregnancy as it yields the highest diagnostic benefit. MRI also lacks ionizing radiation, making a preferred imaging modality to CT or PET. Gadolinium should be avoided during pregnancy secondary to possible risk to the fetus<sup>7,8,9</sup>. MRI, however, is susceptible to artifact and may not be achievable by pregnant patients, who may not be able to breath hold and lay supine for long durations<sup>10,11</sup>.

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# Molar Pregnancy and Gestational Trophoblastic Neoplasia (GTN) (PV-16)

#### Guideline

Molar Pregnancy and GTN (PV-16.1) References (PV-16)

# **Molar Pregnancy and GTN (PV-16.1)**

PV.MP.0016.1.A

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- Molar pregnancy
  - Ultrasound is the initial medically necessary study
  - Once diagnosed on an Obstetrical Ultrasound treatment is usually evacuation.
- Individuals should undergo chest x-ray pre- and post-evacuation.
  - If chest x-ray is positive for metastases, management as per GTN guidelines, see

**Gestational Trophoblastic Neoplasia (GTN) (ONC-22.5)** in the Oncology Imaging Guidelines.

- Serum hCG levels are obtained every 1-2 weeks after treatment of molar pregnancy until they normalize
- Individuals with a molar pregnancy and rising or plateauing hCG levels post evacuation and/or Gestational trophoblastic neoplasia
  - See <u>Gestational Trophoblastic Neoplasia (GTN) (ONC-22.5)</u> in the Oncology Imaging Guidelines.

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# Impotence/Erectile Dysfunction (PV-17)

#### Guideline

Impotence/Erectile Dysfunction (PV-17.1) References (PV-17)

# Impotence/Erectile Dysfunction (PV-17.1)

PV.ED.0017.1.A

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- Imaging depends on the suspected disease and is medically necessary as follows:
  - Penile Doppler ultrasound (CPT® 93980) if erectile dysfunction suspected<sup>2</sup>
  - CTA Pelvis with contrast (CPT® 72191) if large vessel vascular insufficiency is suspected following ultrasound.
  - Duplex ultrasound (CPT® 93980) to assess penile vasculature in Peyronie's disease<sup>1</sup>
  - If male hypogonadism is suspected, See <u>Pituitary (HD-19)</u> in the Head Imaging Guidelines
- Functional MRI or PET studies are not medically necessary for this indication.
- Priapism
  - Penile Doppler Ultrasound (CPT® 93980) is medically necessary if non-ishemic priapism is suspected
  - MRI likely does not have a role in the initial diagnosis of priapism given the time sensitive nature of diagnosis and management
  - In patients with persistent non-ischemic priapism where an embolization may be necessary CTA (CPT® 72191) or MRA Pelvis (CPT® 72198) is medically necessary
  - Penial Doppler Ultrasound (CPT® 93980) is medically necessary post procedure for ischemic priapism
  - If patient has priapism >24-48 hours or refractory to treatment, MRI Pelvis without and with contrast (CPT® 72197) or MRI Pelvis without contrast (CPT® 72195) is medically necessary

#### **Evidence Discussion (PV-17)**

- Erectile dysfunction (ED) may utilize penile Doppler ultrasound to assess penile vasculature. Ultrasound has the advantages of being able to provide robust information about both cavernous arterial inflow and the veno-occlusive capacity of the penis<sup>7</sup>, is readily available, minimally invasive and tolerated well by patients<sup>8</sup>. Advanced imaging with CTA of the pelvis with contrast may be indicated if large vessel vascular insufficiency is suspected. A penile duplex ultrasound may be utilized in the workup of Peyronie's disease<sup>1</sup>.
- Advanced imaging for ED or Peyronie's disease with either PET or functional MRI is considered investigational.
- A penile Doppler ultrasound may be utilized for workup of non-ischemic priapism or post procedure for ischemic priapism<sup>5</sup>. The sensitivity of Doppler ultrasound in localizing an anterior-cavernosal fistula is approximately 100%<sup>4</sup>. If embolization is planned, CTA or MRA of the pelvis may be indicated.

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### References (PV-17)

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# Penis–Soft Tissue Mass (PV-18)

#### Guideline

Penis-Soft Tissue Mass (PV-18.1) References (PV-18)

### Penis-Soft Tissue Mass (PV-18.1)

PV.PM.0018.1.A

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- Penile ultrasound (CPT® 76857) is medically necessary for initial evaluation softtissue lesions of the penis, Duplex (Doppler) scan CPT® 93975 complete; CPT® 93976 limited) is medically necessary as an add-on.
- If primary penile cancer is suspected, biopsy is indicated
  - For further workup of biopsy confirmed penile cancer see Cancers of External Genitalia - Initial Work-up/Staging (ONC-24.6) in the Oncology Imaging Guidelines.
- Peyronie's Disease
  - Ultrasound (CPT® 76857) is medically necessary
  - MRI Pelvis without and with contrast (CPT® 72197) is medically necessary if ultrasound is equivocal and surgery or injection therapy is being contemplated

#### **Evidence Discussion (PV-18)**

- Soft tissue lesions of the penis can be evaluated with penile ultrasound with doppler imaging as an initial evaluation<sup>1</sup>. Ultrasound allows a readily available, non-invasive option for accurate assessment of the vascular and structural features of the penis while avoiding ionizing radiation. Advanced imaging with CT abdomen and pelvis and/or lymphoscintigraphy or SPECT/CT may be indicated for biopsy proven cancer depending on the stage, however is not necessary for the initial workup of a penile mass<sup>2</sup>.
- Peyronie's disease can be initially assessed utilizing ultrasonography<sup>5</sup>. Advanced imaging with MR can be performed after equivocal ultrasound if necessary prior to surgical intervention or injection therapy<sup>6</sup>.

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# Male Pelvic Disorders (PV-19)

#### Guideline

Male Pelvic Disorders (PV-19.1) References (PV-19)

# Male Pelvic Disorders (PV-19.1)

PV.PE.0019.1.U

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- This guideline is intended for the workup of pelvic pain in relation to the male pelvic organs
  - If there is clinical concern for a non-genitourinary cause of pelvic pain please see the most applicable condition-specific guideline (e.g., General Abdomen, General, General Peripheral Vascular Disease, General Nerve and Neuromuscular Disorder Imaging, etc.)
- Chronic Pelvic Pain Syndrome (CPPS)
  - This may include males experiencing chronic perineal pain, bilateral scrotal content pain, penile pain, pelvic pain or pain with ejaculation. See: <u>Scrotal Pathology (PV</u> <u>20.1)</u> for evaluation of scrotal pain as predominant symptom.
  - Workup includes comprehensive history, physical exam, and laboratory studies as well as cystoscopy, urodynamics, and/or imaging when the diagnosis is unclear
    - Transabdominal pelvic ultrasound (bladder and prostate [CPT® 76856 or CPT® 76857]) is medically necessary as initial imaging
    - CT Pelvis with contrast (CPT® 72193) OR MRI Pelvis without contrast (CPT® 72195) OR with and without contrast (CPT® 72197) is medically necessary if ultrasound is equivocal or nondiagnostic and alternative clinical conditions are being considered
- Prostate
  - Prostate Disorders
    - Suspected Benign Prostatic Hypertrophy with obstructive voiding symptoms:
      - Transrectal ultrasound (CPT® 76872) or Pelvis transabdominal ultrasound (bladder and prostate [CPT® 76856 or CPT® 76857]) is medically necessary.
    - For prostatitis with urinary retention or suspected abscess any of the following imaging studies are medically necessary:
      - Transrectal ultrasound (CPT® 76872) or Pelvis transabdominal ultrasound (bladder and prostate [CPT® 76856 or CPT® 76857])
      - CT Pelvis with contrast (CPT® 72193) or MRI Pelvis without contrast (CPT® 72195) or with and without contrast (CPT® 72197) if ultrasound is equivocal for abscess or mass
  - Prostate Artery Embolization (PAE)
    - MRA Pelvis (CPT® 72198) or CTA Pelvis (CPT® 72191) is medically necessary for evaluation of the pelvic vasculature if:
      - prostate artery embolization is planned

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- The vascular embolization code (CPT® 37243) is inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention.
  - Additional advanced imaging codes are not medically necessary during the procedure to complete the intervention.

#### Testicular

- Hematospermia, transrectal ultrasound (TRUS) (CPT® 76872) is medically necessary as the initial imaging study in all cases.
  - MRI Pelvis without contrast (CPT® 72195) or MRI Pelvis without and with contrast (CPT® 72197) is medically necessary to evaluate:
    - Suspected hemorrhage within the seminal vesicles
    - Radiation injury, neoplasia
    - Failure of conservative treatment for 2 weeks
    - Abnormal findings on Transrectal ultrasound

#### Rectal

- Proctalgia Syndromes
  - Prior to advanced imaging, the evaluation of rectal/perineal pain should include:
    - Digital rectal examination (assess for mass, prostate, fissures, hemorrhoids, etc.)
    - Recent flexible sigmoidoscopy or colonoscopy subsequent to the start of reported symptoms to exclude inflammatory conditions or malignancy
  - Endoanal ultrasound (CPT® 76872), MRI Pelvis without and with contrast (CPT® 72197), or CT Pelvis with contrast (CPT® 72193)is medically necessary after the above studies have been performed or if laboratory or clinical information suggest infection, abscess, or inflammation
- MRI (MRI Pelvis without contrast CPT® 72195) for Defecography is considered investigational/experimental by UHC

#### Bladder

- Work-up of interstitial cystitis/bladder pain syndrome (IC/BPS) may include history, physical exam, laboratory exam (urinalysis and urine culture), cystoscopy, and measurement of post void residual urine by bladder catheterization
  - Pelvic ultrasound (CPT® 76856 or CPT® 76857) is medically necessary
    - CT Pelvis with contrast (CPT® 72193) is medically necessary if ultrasound is equivocal for complicated interstitial cystitis/bladder pain syndrome

#### **Background and Supporting Information**

• The proctalgia syndromes are characterized by recurrent episodes of rectal/perineal pain, and may be due to sustained contractions of the pelvic floor musculature.

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#### **Evidence Discussion (PV-19)**

- For individuals with lower urinary tract symptoms suspected to be caused by Benign Prostatic Hypertrophy ultrasound is the modality of choice for evaluation. It allows for assessment of bladder volume and post-void residual as well as intravesical prostatic protrusion<sup>6</sup>. Ultrasound is advantageous as it is readily available, effective, and free of ionizing radiation.
- Prostate Artery Embolization is an excepted treatment for the management of lower urinary tract symptoms according to the American Urological Association<sup>11</sup>. Imaging is indicated for further delineation of the pelvic vasculature to aid in preprocedure surgical planning. The accuracy of CTA to identify the Prostate artery has been shown to approximately 97%<sup>13</sup>. MRI angiography has been shown to identify the prostate artery in 76% of cases, has been helpful in identifying malignancy when suspected and does not carry the risk of radiation exposure<sup>13</sup>.
- Transrectal ultrasound is supported for the initial diagnostic imaging for hematospermia<sup>2</sup>. Ultrasound has high sensitivity for detecting abnormalities of the prostate and seminal tract, demonstrating abnormalities in 82-95% of men with hematospermia<sup>2</sup>. Ultrasound is advantageous as it is readily available, effective, and free of ionizing radiation. It also allows for simultaneous aspiration or biopsy of any lesions detected. MRI is a useful adjunct to ultrasound imaging. CT has limited value in the evaluation of hematospermia due to its limited ability to differentiate structural changes of the prostate and seminal tract and its lack of soft-tissue contrast<sup>2</sup>.
- In individuals with suspected Proctalgia initial evaluation should include a through exam, including digital rectal exam and direct visualization with sigmoidoscopy or colonoscopy to exclude other causes of rectal pain. Clinical history and normal digital rectal exam is often sufficient to make a diagnosis of Proctalgia<sup>7</sup>. If infection, abscess or inflammation is suspected imaging is indicated<sup>15</sup>.
- The work up for interstitial cystitis/bladder pain syndrome (IC/BPS) should include a careful history, physical and laboratory examination <sup>16</sup>. Additional testing such as radiologic imaging should be undertaken only when it will alter the treatment approach <sup>16</sup>. Ultrasound may be useful for adjunct diagnosis <sup>17</sup> and has the advantages of being widely available and without ionizing radiation. Additional testing with CT may be appropriate when ultrasound results are inconclusive but bears the risk of ionizing radiation.

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# Scrotal Pathology (PV-20)

#### Guideline

Scrotal Pathology (PV-20.1) Paratesticular and spermatic cord masses (PV-20.2) Testicular Microlithiasis (PV-20.3) References (PV-20)

# **Scrotal Pathology (PV-20.1)**

PV.SP.0020.1.A

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- Scrotal pain or mass
  - Scrotal ultrasound (CPT® 76870) and/or Duplex (Doppler) ultrasound (CPT® 93975 or CPT® 93976) for initial evaluation
  - MRI Pelvis without and with contrast (CPT® 72197) or Tc-99m scrotal scintigraphy (CPT® 78761) is medically necessary if ultrasound is inconclusive.
- Scrotal pain and hydrocele with suspicion of hernia
  - See Inguinal or Femoral Hernia, or Indeterminate <u>Groin Pain (AB-12.1)</u> in the Abdomen guidelines
- Cryptorchidism/undescended testis in the adult.
  - Scrotal ultrasound (CPT 76870), MRI Pelvis without and with contrast (CPT® 72197), or CT Pelvis with contrast (CPT® 72193)
- Variocele evaluation
  - Scrotal ultrasound and/or Duplex (Doppler) ultrasound (CPT® 76870 and/or CPT® 93975 or CPT® 93976) of the scrotum with color flow mapping in supine and upright positions is medically necessary to assess venous reflux into plexus pampiniformis if varicocele suspected (for example, in inguinal hernia evaluation)
  - CT Abdomen and Pelvis with contrast (CPT® 74177) is medically necessary for right-sided varicocele, when there is suspicion for intra-abdominal pathology

#### **Background and Supporting Information**

 The causes of scrotal pain may include torsion, epididymitis, strangulated hernia, segmental testicular infarction, trauma, testicular tumor, and idiopathic scrotal edema.<sup>1</sup>

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# Paratesticular and spermatic cord masses (PV-20.2)

PV.SP.0020.2.A

- Scrotal ultrasound (CPT® 76870) is medically necessary as the initial imaging procedure.
  - MRI Pelvis without and with contrast (CPT® 72197), exploration and biopsy are additional considerations if ultrasound is inconclusive.

# **Testicular Microlithiasis (PV-20.3)**

PV.SP.0020.3.A

- Scrotal ultrasound (CPT® 76870) is medically necessary for initial evaluation
- Annual Scrotal ultrasound (CPT® 76870) follow-up is medically necessary only if a risk factor is present which include:
  - Family history of germ cell tumor
  - Maldescent
  - Orchidopexy
  - Testicular atrophy
- For personal history of germ cell tumor See <u>Testicular</u>, <u>Ovarian and Extragonadal</u>
   <u>Germ Cell Tumors</u> (<u>ONC-20</u>) in the Oncology Imaging Guidelines

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# Fistulae, Abscess, and Pilonidal Cyst (PV-21)

#### Guideline

Fistula in Ano (PV-21.1) Abscess (PV-21.2) Pelvic Fistula (PV-21.3) Pilonidal Cyst (PV-21.4) References (PV-21)

# Fistula in Ano (PV-21.1)

PV.PA.0021.1.A

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- MRI Pelvis without and with contrast (CPT® 72197) is medically necessary.
  - If MRI cannot be performed, endoscopic ultrasound is superior, and thus preferential, to CT imaging.
  - CT Pelvis with contrast (CPT® 72193) is an inferior study to either of the above (accuracy of endoscopic ultrasound vs. CT for perianal fistula is 82% vs. 24%) and it is medically necessary only in circumstances in which MRI and endoscopic ultrasound cannot be performed.

#### **Evidence Discussion (PV-21.1)**

- Anorectal fistulas most commonly arise from abscesses that originate in the anal crypts (90%). Physical exam will frequently identify these but advanced imaging is often needed to determine the course of the fistulous tract, its relationship with the sphincteric musculature and associated infection/abscess<sup>11</sup>. Because of its superior resolution, MRI is the preferred modality, followed by endoscopic ultrasound and then CT<sup>1</sup>.
- Non-iatrogenic anal fistula located in atypical positions (lateral) suggest the possibility of Crohn's disease. See IBD Perirectal/Perianal disease (AB-23.3).

# Abscess (PV-21.2)

PV.PA.0021.2.A

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- Perirectal Abscess
  - MRI Pelvis without and with contrast (CPT® 72197) is the preferred study
    - CT Pelvis with contrast (CPT® 72193) is medically necessary as an alternative study if desired.
  - For the evaluation of Perianal and Perirectal Disease related to Crohn's Disease, See Perirectal/Perianal Disease (AB-23.3) in the Abdomen Imaging Guidelines.
- Perineal Abscess
  - Fournier Gangrene
    - Diagnosis commonly made on the basis of clinical and physical exam
    - CT Pelvis, contrast as requested, is medically necessary for evaluating extent of disease for surgical planning
- Vulvar Abscess
  - CT Pelvis, contrast as requested, is medically necessary to delineate the extent of a vulvar abscess and evaluate surrounding structures for surgical planning
  - MRI Pelvis without and with contrast (CPT® 72197) may also be medically necessary for surgical planning

#### **Evidence Discussion (PV-21.2)**

- · Pelvic infections can take the form of intraperitoneal abscesses or perineal wall infections <sup>12</sup>.
- Refer to Abdominal Sepsis (AB-3-1) for intraabdominal pelvic abscess.
- History and physical can usually identify perineal (perirectal and perianal) abscesses<sup>12</sup>. Due to a high rate of recurrence due to associated fistulous tracts, advanced imaging with MRI (preferred because of its improved resolution), endorectal ultrasound or CT scan<sup>1,11</sup>. Primary treatment is surgical drainage<sup>1,12</sup>.

## Pelvic Fistula (PV-21.3)

PV.PA.0021.3.A

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- History and physical exam (to include pelvic and/or anorectal examination):
  - Rectovesicular Fistula the following are medically necessary:
    - MRI Pelvis with and without contrast (CPT® 72197) OR
    - CT Pelvis with contrast (CPT® 72193)
  - Vaginal Fistula:
    - Enterovaginal, Colovaginal, Rectovaginal or Anovaginal:
      - Anoscopy and/or proctoscopy
      - Endoanal ultrasound (rarely used)
      - MRI Pelvis with and without contrast (CPT® 72197) is medically necessary as the initial modality for suspected enterovaginal fistula
      - CT Pelvis with contrast (CPT® 72193) is medically necessary if:
        - MRI contraindicated OR urgent evaluation of acute diverticulitis OR early postoperative period
    - Urinary Vaginal Fistula (Ureterovaginal, Vesicovaginal, or Urethrovaginal) the following are medically necessary:
      - Cystoscopy
      - CT urography (CT Abdomen and Pelvis without and with contrast CPT® 74178) and/or CT cystography (CT Pelvis without contrast CPT® 72192) or
      - MRI Pelvis with and without contrast (CPT® 72197)

#### **Background and Supporting Information**

- A vaginal fistula is an abnormal communication between the vagina and either a portion of the digestive system or the urinary tract
  - Causes of vaginal fistula may include IBD, endometriosis, infection, tumor, radiation, obstetrical trauma and surgical injuries.
  - Symptoms of vaginal fistula-Persistent vaginitis, dyspareunia, perineal dermatitis. foul-smelling vaginal discharge, and/or urinary or fecal incontinence.
- A rectovesicular fistula is an abnormal communication between the rectum and the bladder.
  - Causes of rectovesicular fistula may include chronic infection, cancer, diverticulitis, IBD, radiation and surgical injuries.
  - Symptoms of rectovesicular fistula-Bubbles in the urine, brown or cloudy urine, blood in the urine, painful urination, recurrent urinary tract infection, and/or abdominal pain

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#### **Evidence Discussion (PV-21.3)**

- MRI has been established as a method of delineating vaginal fistulas. This is secondary to its excellent soft tissue resolution, allowing identification of acute inflammatory changes, post-surgical fibrosis, neoplastic tissue and abscesses<sup>3</sup>. It also has the benefit of lacking ionizing radiation, but may have limited access as compared with CT. MRI is also contraindicated by the presence of metallic foreign body or MRI-incompatible devices, such as some pacemakers<sup>3</sup>. Studies have shown a positive predictive value of 92% for delineation of anorectal vaginal fistulas<sup>4</sup>.
- CT can also be utilized in the visualization of fistulas<sup>3,6</sup>. It does have lower contrast resolution than MRI<sup>3</sup> and does carry the risk of ionizing radiation. It may be beneficial in emergent situations given the wide availability or in situations where an MRI is contraindicated. CT-urography/cystography is also a mainstay in evaluation of the urinary tract and can be utilized to evaluate urinary vaginal fistulas<sup>3</sup>.

# Pilonidal Cyst (PV-21.4)

PV.PA.0021.4.A

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- Advanced imaging is not medically necessary for pilonidal cyst disease<sup>9</sup>.
  - History and physical exam are sufficient for diagnosis of pilonidal cyst.
- If other underlying etiologies are suspected, refer to appropriate guidelines:
  - For suspected osteomyelitis, see: General Infection/Osteomyelitis (MS-9.1) in the Musculoskeletal Imaging Guidelines
  - For abdominal fistulae, see: Fistulae (AB-48) in the Abdomen Imaging Guidelines
  - For suspected spinal dysraphism, see: Cutaneous Indications to Suspect Occult Spinal Dysrpahism (PEDSP-4.2) in the Pediatric Spine Imaging Guidelines

#### **Evidence Discussion (PV-21.4)**

 Pilonidal cysts most frequently arise in the natal cleft, the groove between the buttocks overlying the sacral area. Asymptomatic disease usually does not require any treatment. Acute and chronic infections can be evaluated sufficiently with history and physical alone<sup>9</sup>. Advanced imaging is limited to concern for complicated disease (See General Infection/Osteomyelitis - MS-9.1).

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# Urinary Incontinence/ Pelvic Prolapse/Fecal Incontinence (PV-22)

#### Guideline

Urinary Incontinence – Initial Imaging (PV-22.1)
Urinary Incontinence – Further Imaging (PV-22.2)
Pelvic Prolapse (PV-22.3)
Fecal Incontinence (PV-22.4)
References (PV-22)

# Urinary Incontinence – Initial Imaging (PV-22.1)

PV.IN.0022.1.A

v1.0.2026

- Initial Imaging, associated with other evaluations, are medically necessary as follows:
  - Non-Neurogenic Incontinence
    - Measurements of post void residual urine by Bladder ultrasound (CPT® 51798)
       OR Bladder catheterization
    - In addition to post void residual volume determination, screening for UTI should be considered
  - Neurogenic Incontinence
    - Ultrasound urinary tract (CPT® 76770 or CPT® 76775)

#### **Background and Supporting Information**

Urinary incontinence can be "stress," "urgency," or mixed; neurogenic or nonneurogenic; and complicated or uncomplicated. Neurogenic incontinence can occur from cerebral, spinal or peripheral neurological diseases.

#### **Evidence Discussion (PV-22.1)**

- The workup of urinary incontinence involves a thorough history and physical examination<sup>2,6</sup>. For incontinence due to non-neurogenic causes, advanced imaging is rarely necessary in the initial evaluation<sup>2</sup>. Assessment of the urine post void residual may be completed either with bladder ultrasound or urethral catheterization<sup>6</sup>.
- Baseline imaging should be obtained in the evaluation of neurogenic urinary incontinence with renal bladder ultrasound 14.

# Urinary Incontinence – Further Imaging (PV-22.2)

PV.IN.0022.2.A

v1.0.2026

- CT Abdomen and Pelvis, contrast as requested, or CT Pelvis, contrast as requested, is medically necessary for any of the following:
  - Abnormality on ultrasound that requires further evaluation
  - Complicated incontinence
    - Failed conservative treatment
    - Pain or dysuria
    - Hematuria
    - Recurrent infection
    - Previous radical pelvic surgery
    - Suspected fistula
    - Suspected mass
    - Previous pelvic or prostate irradiation
  - Suspected fistulae
  - Detecting ectopic ureters if ultrasound is non-diagnostic
  - Pre-operative planning for complicated incontinence when ordered by or in consultation with the operating physician
- For neurogenic urinary incontinence See <u>Red Flag Indications (SP-1.2)</u> and <u>Myelopathy (SP-7.1)</u> in the Spine Imaging Guidelines and <u>Dementia (HD-8.1)</u> and <u>Normal Pressure Hydrocephalus (NPH) (HD-8.4)</u> in the Head Imaging Guidelines.

#### **Evidence Discussion (PV-22.2)**

- Urinary incontinence that has failed a trial of conservative treatment may require advanced imaging with CT of the abdomen and/or pelvis with or without contrast<sup>2</sup>.
   Advanced imaging may also be ordered for pre-operative planning if requested by the surgeon or to follow up on an abnormality noted on previous ultrasound<sup>6</sup>.
- Other clinical scenarios where advanced imaging may be medically necessary are incontinence occurring concomitantly with abdominal or pelvic pain, dysuria or hematuria, or in the setting of recurrent urinary tract infections<sup>2</sup>. Incontinence in the setting of previous radical pelvic surgery or radiation may also require advanced imaging<sup>14</sup>.
- If there is suspicion of a fistula, mass, or ectopic ureters (and ultrasound is non-diagnostic), advanced imaging with CT may be indicated<sup>6</sup>.

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### Pelvic Prolapse (PV-22.3)

PV.IN.0022.3.U

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- Transvaginal (TV) ultrasound (CPT® 76830) and/or Transperineal ultrasound (CPT® 76872) is medically necessary as the initial study of choice
  - Pelvic ultrasound (CPT® 76856 or CPT® 76857) is medically necessary if requested as a complimentary study.
- Urodynamic testing may be helpful if there is incontinence with a stage II or greater prolapse or voiding dysfunction
- MRI Pelvis (CPT® 72195 or CPT® 72197) is medically necessary for the following:
  - Pelvic floor anatomy and pelvic organ prolapse evaluations if exam and TV ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76856 or CPT® 76857) are equivocal; or
  - Pre-operative planning for complex organ prolapse when ordered by or in consultation with the operating physician; or
  - Persistent incontinence following surgery
- Mesh and Graft complications
  - Diagnostic evaluation for mesh and graft complications may include colonoscopy, cystoscopy, and/or urodynamics
  - Transvaginal (TV) ultrasound (CPT® 76830) and/or Pelvic ultrasound (CPT® 76856 or CPT® 76857), CT Abdomen and/or Pelvis, contrast as requested, MRI Pelvis without contrast or without and with contrast (CPT® 72195 or CPT® 72197) are medically necessary depending on the mesh and graft complication
- Sacral osteomyelitis may be a complication of sacrocolpopexy. MRI Pelvis with and without contrast (CPT® 72197) is medically necessary for lower back pain and/or suspected sacral osteomyelitis after this procedure.
- MRI (MRI Pelvis without contrast CPT® 72195) for Defecography is considered investigational/experimental by UHC.

#### **Evidence Discussion (PV-22.3)**

- The mainstay of evaluation of pelvic organ prolapse remains clinical pelvic examination. This allows for direct evaluation of prolapse and calculation prolapse quantification<sup>3,15</sup>.
- Translabial, transperineal or transvaginal ultrasound have shown correlation with<sup>3,15</sup>.
   Ultrasound also allows for real-time evaluation, has wide availability, fast access, and lack of ionizing radiation exposure.
- MRI has been shown to have excellent soft tissue delineation. It circumstances were clinical exam and ultrasound are equivocal, MRI may provide additional information for conditions such as enterocele, sigmoidocele and intussusception<sup>15</sup>.

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- Complications related to mesh and graft placement in pelvic floor surgery are diverse in nature<sup>4</sup>. Work up for suspected complication is complex and may include a diverse range of diagnostic procedures such as radiologic imaging, cystoscopy, and colonoscopy. Surgical meshes have variable visibility 12. Given the varied nature of this these complications modality of imaging should be tailored to suspected complication.
- A known rare complication of sacrocolpopexy is sacral osteomyelitis. In cases of suspected osteomyelitis, MRI is the preferred imaging as it has a very high sensitivity for detection infection, especially in early stages 12.

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# **Fecal Incontinence (PV-22.4)**

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The evaluation of fecal incontinence generally proceeds as follows:

- Determine the severity of the incontinence (Bristol Stool Scale, Fecal Incontinence Severity Index, etc.)
- History and Physical to include digital rectal examination and perianal pinprick (to assess for neurogenic causes)
- Trial of conservative management
- Diagnostic Testing if symptoms persist to include:
  - Ano-rectal Manometry
  - Balloon Expulsion Test
  - Endoanal ultrasound (CPT® 76872) to confirm sphincter defects in individuals with suspected sphincter injury (e.g. history of vaginal delivery or anorectal surgery)
  - MRI Pelvis (CPT® 72197) is medically necessary if:
    - Ano-rectal manometry suggests weak sphincter pressures AND/OR there is an abnormal balloon expulsion test AND
    - There has been a failure of a trial of conservative management since the onset of or change in symptoms AND
    - Surgery is being considered
- MRI (MRI Pelvis without contrast (CPT® 72195) for Defecography is considered investigational/experimental by UHC.

#### **Background and Supporting Information**

With regards to fecal incontinence ACG Guidelines stated that "the internal sphincter is visualized more clearly by endoanal ultrasound, whereas MRI is superior for discriminating between an external anal sphincter tear and a scar and for identifying external sphincter atrophy.

However, guidelines adopted by the American Society of Colon and Rectal Surgeons stated that "Endoanal ultrasound is a useful and sensitive tool in the evaluation of patients with FI (fecal incontinence), especially when there is a history of vaginal delivery or anorectal surgery. Ultrasound can reliably identify internal and external sphincter defects that may be associated with sphincter dysfunction." In addition, the guidelines note "Other modalities (eg, MRI) have shown substantial interobserver variability and, at this point, are likely inferior to ultrasound imaging, but they may provide additional information where endoanal ultrasound is unavailable."

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#### **Evidence Discussion (PV-22.4)**

- According to the American College of Gastroenterology, the American Society of Colon and Rectal Surgeons and the American College of Obstetrics and Gynecology, complete history and physical exam is essential for the evaluation of patient with fecal incontinence<sup>1,5,10</sup>.
- For individuals that fail conservative measures, ano-rectal manometry and rectal balloon expulsion testing should be performed. This may help to guide additional treatment and diagnostic testing<sup>1</sup>.
- Endoanal ultrasound (EAUS) can be considered in individuals with suspected sphincter injury<sup>1,5</sup>. Ultrasound is widely available and well tolerated, however it is operator-dependent<sup>16</sup>. EAUS shows very good interobserver agreement in the diagnosis of sphincter defects and the measurement of the internal anal sphincter<sup>16</sup>.
- MRI has also emerged as an imaging modality for evaluation of fecal incontinence. While EAUS is superior for the evaluation of the internal anal sphincter, MRI shows better distinction between fat and muscle in the evaluation of the external anal sphincter<sup>16</sup>. MRI is limited by the fact that it is not as readily available and is unsuitable for patients with limiting conditions such as metal implants and claustrophobia<sup>16</sup>. MRI defecography also may play a role in the evaluation of fecal incontinence as it allows for insight into important functional disorders related to defecation<sup>16</sup>.

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# Patent Urachus (PV-23)

Guideline

Patent Urachus (PV-23.1) References (PV-23)

# Patent Urachus (PV-23.1)

PV.UR.0023.1.A

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- Drainage from the umbilicus, redness around umbilicus, abdominal pain, or urinary tract infection from persistent fetal connection between the bladder and the umbilicus:
  - Ultrasound (CPT® 76856 or CPT® 76857 and/or CPT® 76700 or CPT® 76705) or voiding cystourethrography (VCUG) (CPT® 74455) is medically necessary for suspected patent urachus
  - CT Pelvis with contrast (CPT® 72193) or MRI Pelvis without contrast (CPT® 72195) or with and without contrast (CPT® 72197) is medically necessary if the ultrasound is equivocal or if additional imaging is needed for surgical planning if there is a suspected urachal carcinoma or other urachal abnormality.

#### **Evidence Discussion (PV-23)**

- A patent urachus (connecting bladder to umbilicus) can manifest as redness around or drainage from the umbilicus, abdominal pain, or urinary tract infections<sup>1</sup>.
- If suspected, ultrasound is indicated as the initial evaluation as it can be diagnostic without exposing the patient to radiation<sup>2,3</sup>.
- Advanced imaging of the pelvis is indicated for inconclusive ultrasound or for surgical planning<sup>1,3</sup>.

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# Bladder Mass (PV-24)

Guideline

Bladder Mass (PV-24.1) References (PV-24)

## Bladder Mass (PV-24.1)

PV.BL.0024.1.A

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- Bladder masses incidentally found on other imaging (ultrasound, cystoscopy or KUB):
  - CT Pelvis without contrast (CPT® 72192) for suspected bladder stone is medically necessary if initial imaging is equivocal or if surgery is planned
  - CT Pelvis without (CPT® 72192) is medically necessary for suspected bladder diverticuli
- See Oncology Imaging Guidelines for biopsy confirmed or suspected malignancy

#### **Background and Supporting Information**

Symptoms of bladder mass may include hematuria, urgency, frequency, chronic urinary infection, obstruction or urinary retention.

#### **Evidence Discussion (PV-24.1)**

- Symptoms of bladder mass may include hematuria, urgency or frequency of urination, urinary infection or urinary retention 1,4,5.
- Bladder masses may be found incidentally on initial imaging such as ultrasound, cystoscopy or KUB (Kidney, Ureter and Bladder X-ray).
- Suspected bladder stone may be further evaluated with CT pelvis if initial imaging is inconclusive or for surgical planning<sup>5</sup>. CT has a higher sensitivity than ultrasound for bladder stones<sup>5</sup>.
- Suspected bladder diverticuli can be further evaluated with CT pelvis 1,4.

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# Ureteral and/or Bladder Trauma or Injury (PV-25)

#### Guideline

Ureteral and/or Bladder Trauma or Injury (PV-25.1) References (PV-25)

# **Ureteral and/or Bladder Trauma or Injury** (PV-25.1)

PV.BT.0025.1.A

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- Abdominal and/or Pelvic ultrasound (CPT® 76700 and/or CPT® 76856) is medically necessary if requested
- CT cystography (CT Pelvis without contrast CPT® 72192) is medically necessary for suspected bladder injury
- CT Abdomen and Pelvis with OR with and without contrast (CPT® 74177 or CPT® 74178) is medically necessary if:
  - Suspected iatrogenic/operative injury OR
  - Blunt trauma and suspected bladder or ureteral injury with one or more of the following (See Blunt Abdominal Trauma (AB-10.1) in the Abdomen Imaging Guidelines):
    - Abdominal pain or tenderness
    - Pelvic or femur fracture
    - Hematocrit <30%</li>
    - Hematuria
    - Non-examinable individual (intoxicated, less than fully conscious, Glasgow Coma Scale Score >13, etc.)
    - Evidence of abdominal wall trauma or seat-belt sign
    - Rapid deceleration injury

#### **Background and Supporting Information**

Bladder trauma: CT cystography- CT Pelvis without contrast allowing the radiologist or Urologist to instill contrast to r/o bladder injury and/or perforation.

Ureteral injury: "latrogenic ureteral injuries can occur during gynecologic, obstetric, urologic, colorectal, general, or vascular surgery; gynecologic surgery accounts for more than half of all iatrogenic injuries."2

#### **Evidence Discussion (PV-25)**

- Ultrasound can performed for suspected ureteral and/or bladder trauma. It may aid in triage of injuries and may lead to immediate surgical intervention rather than additional imaging. However it has lower sensitivity compared to CT, particularly in genitourinary injury<sup>4</sup>.
- For individuals with suspected bladder injury retrograde cystography is appropriate<sup>2</sup>. CT cystography has a reported 95-100% sensitivity and specificity for the diagnosis of

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bladder rupture<sup>3,4</sup>. It has the benefits of being widely available and accurate, but does have exposure to ionizing radiation.

 Those presenting with suspected ureteral injury CT of the abdomen and pelvis is appropriate for evaluation of the complete urinary tract. Imaging with contrast is preferred for evaluation of as it has higher sensitivity for detecting concurrent visceral organ and vascular injuries<sup>3</sup>. Urogram is helpful in further evaluation of the ureters<sup>2</sup> as it may show contrast extravasation from the ureter or partial or complete ureteral obstruction<sup>1</sup>.

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# Policy History and Instructions for Use

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Policy History and Instructions for Use

# **Policy History and Instructions for Use**

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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<sup>®</sup> for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual<sup>®</sup> does not have applicable criteria, United HealthCare Services, Inc. may also use United HealthCare Services, Inc. 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. 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