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Clinical Appropriateness Guidelines

Advanced Imaging

Appropriate Use Criteria: Imaging of the Abdomen and Pelvis

Proprietary

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Description and Application of the Guidelines

The Carelon Clinical Appropriateness Guidelines (hereinafter "the Carelon Clinical Appropriateness Guidelines" or the "Guidelines") are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. As used by Carelon, the Guidelines establish objective and evidence-based criteria for medical necessity determinations where possible. In the process, multiple functions are accomplished:

- To establish criteria for when services are medically necessary (i.e., in general, shown to be effective in improving health outcomes and considered the most appropriate level of service)
- · To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To advocate for patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

The Carelon guideline development process complies with applicable accreditation standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up-to-date clinical principles and best practices. Relevant citations are included in the References section attached to each Guideline. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website twenty-four hours a day, seven days a week. Copies of the Carelon Clinical Appropriateness Guidelines are also available upon oral or written request. Although the Guidelines are publicly-available, Carelon considers the Guidelines to be important, proprietary information of Carelon, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of Carelon.

Carelon applies objective and evidence-based criteria, and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The Carelon Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient's unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient's condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines. If requested by a health plan, Carelon will review requests based on health plan medical policy/guidelines in lieu of the Carelon Guidelines. Pharmaceuticals, radiotracers, or medical devices used in any of the diagnostic or therapeutic interventions listed in the Guidelines must be FDA approved or conditionally approved for the intended use. However, use of an FDA approved or conditionally approved product does not constitute medical necessity or guarantee reimbursement by the respective health plan.

The Guidelines may also be used by the health plan or by Carelon for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

General Clinical Guideline

Clinical Appropriateness Framework

Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention should outweigh any potential harms that may result (net benefit).
- Current literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- Based on the clinical evaluation, current literature, and standards of medical practice, there exists a
 reasonable likelihood that the intervention will change management and/or lead to an improved
 outcome for the patient.

If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would supersede the requirements set forth above. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account.

Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

Repeat Diagnostic Intervention

In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing at the same facility due to technical issues
- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns
- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study

 Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

Repeat Therapeutic Intervention

In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered.

Imaging of the Abdomen and Pelvis

General Information/Overview

Scope

These guidelines address advanced imaging of the abdomen and pelvis in both adult and pediatric populations. For interpretation of the Guidelines, and where not otherwise noted, "adult" refers to persons age 19 and older, and "pediatric" refers to persons age 18 and younger. Where separate indications exist, they are specified as Adult or Pediatric. Where not specified, indications and prerequisite information apply to persons of all ages.

See the Coding section for a list of modalities included in these guidelines.

Technology Considerations

Advanced imaging is an umbrella term that refers to anatomy-based (structural), physiology-based (functional), and hybrid imaging methods that offer greater spatial and/or contrast resolution relative to conventional imaging methods in radiology such as radiography or ultrasound. Examples of advanced structural imaging include computed tomography (CT) and magnetic resonance imaging (MRI) and some technique variants. Advanced functional imaging includes nuclear medicine and molecular imaging techniques such as scintigraphy, single photon emission computed tomography (SPECT), and positron emission tomography (PET) as well as those MRI/CT technique variants that create image contrast based on a physiological parameter (for example, functional magnetic resonance imaging (fMRI). Hybrid advanced imaging techniques optimize diagnostic accuracy by coupling structural and functional approaches (such as PET-CT or PET-MRI).

Ultrasound is the initial imaging modality of choice for many conditions of the abdomen and pelvis, including hepatobiliary, urinary tract, and gynecologic conditions. While ultrasound is operator dependent and image quality may be impacted by obesity and bowel gas, accuracy, availability and absence of ionizing radiation make it an ideal choice for initial evaluation of several intra-abdominal conditions, especially in the right upper quadrant and in the pelvis and especially in pediatric patients and pregnant women.

Computed tomography (CT) is often utilized for imaging the abdomen and pelvis. It provides excellent 3-dimensional resolution and can be performed relatively quickly, reducing the potential for motion artifact. A major drawback of CT is the dose of ionizing radiation required for image acquisition, which is of particular concern in younger patients and those who require multiple scans over time.

CT may be performed with or without contrast; contrast provides additional detail to delineate vascular and gastrointestinal structures and is recommended in certain settings, such as infection, tumor, hemorrhage and visceral lesions. However, contrast increases scan acquisition time, and confers risk in cases of impaired renal function, pregnancy, metformin use, radioactive iodine treatment for thyroid disease, or previous reactions to contrast agents. Noncontrast CT may often suffice in some situations, and is preferred when evaluating for intraabdominal hemorrhage and/or calcification.

Magnetic resonance imaging (MRI) requires a longer time for image acquisition and is more prone to motion artifact than CT. However, MRI does not expose patients to ionizing radiation and has better contrast resolution than CT. MRI may be a useful substitute in cases where contrast CT is contraindicated. It is often preferred in pediatric patients due to the absence of radiation; however, sedation may be required in younger patients in order to obtain adequate images.

MRI may be performed with or without contrast. Use of contrast is recommended for imaging of vascular structures or solid organs. The most commonly used agent for contrast MRI is gadolinium, but iron oxide and iron platinum contrast agents are also available. Administration of gadolinium has been associated with a rare but serious condition known as nephrogenic systemic fibrosis, and should be avoided in persons with advanced renal disease. Gadolinium contrast has also recently been shown to accumulate within the brain parenchyma, a finding of uncertain clinical significance. There are a number of alternative contrast agents which have been developed for

specialized use including gadoxetic acid (hepatobiliary imaging), gadofosveset (a blood pool agent), and gadobutrol (an extracellular fluid agent).

The use of contrast is at the discretion of the ordering provider and/or the radiologist performing the imaging study, and should be tailored to the individual circumstances of each case.

Magnetic resonance cholangiopancreatography (MRCP) is a noninvasive alternative to endoscopic retrograde cholangiopancreatography (ERCP). MRCP avoids the risks associated with anesthesia and does not expose patients to ionizing radiation. It is able to detect extraductal abnormalities and can provide better visualization of structures proximal to a ductal obstruction. However, it is prone to motion artifact, may be less able to detect subtle abnormalities, and—unlike ERCP—has no therapeutic capabilities.

Dynamic pelvic MRI yields a 3-dimensional image used to evaluate the pelvic floor and rectal function by imaging pelvic muscles at rest and while contracted. Magnetic resonance defecography is a form of dynamic MRI used for evaluation of pelvic organ and muscle function through imaging stages of defecation. Dynamic pelvic MRI may be indicated in cases of pelvic organ prolapse, pelvic pain, and fecal and urinary incontinence.

CT enterography and MR enterography are noninvasive, cross-sectional imaging modalities protocolled to optimize visualization of the small intestine. CT enterography provides images of the entire small intestine without interference from overlapping loops, and detects both extraluminal and luminal disease. MR enterography also provides high-contrast resolution; it can detect abscesses and fistulas, and can distinguish fibrotic from inflammatory structures. In general, CT enterography is preferred for extraluminal pathology, whereas MR enterography is preferred for organ-specific and disease-specific (such as Crohn's disease) evaluation.

Imaging of the urinary tract often begins with **kidney**, **ureter**, **and bladder** (**KUB**) **radiography**. This type of radiograph is particularly useful in acute care settings for evaluation of diffuse pain, or pain suggestive of renal or urinary tract disease. **Ultrasound** is also useful for initial evaluation and avoids the risks associated with radiation exposure. Both ultrasound and KUB radiography may be used for follow-up of nephrolithiasis in select patients.

CT abdomen/pelvis stone protocol (CT KUB), a noncontrast CT scan that images the kidney, ureters, and bladder, is commonly used for visualizing the urinary tract. Indications for CT KUB include urolithiasis/nephrolithiasis, renal parenchymal calcifications, and exclusion of hemorrhagic changes. Low-dose CT can also be used to scan for urinary tract stones with a lowered effective radiation dose. Compared to standard CT, low-dose CT still has excellent sensitivity, but image resolution can suffer, especially in the case of urinary tract stones under 3 mm in size.

CT urography (CTU, also referred to as CT IVP or CT IVU) is a more complex variant of CT that is used to evaluate the urinary tract. While CT KUB is simply a noncontrast CT scan, CT urogram includes an initial noncontrast CT scan followed by contrast-enhanced nephrographic phase and excretory phase imaging. CT urogram combines conventional CT with thin-section axial CT images taken during the excretory phase. Historically, CT was combined with excretory urography (EU) for CT urogram, but this method is no longer standard. CT urogram can be used to evaluate various tumor types, papillary necrosis, and renal inflammatory disease, among other conditions.

Definitions

Phases of the care continuum are broadly defined as follows:

- Screening testing in the absence of signs or symptoms of disease
- Diagnosis testing based on a reasonable suspicion of a particular condition or disorder, usually due
 to the presence of signs or symptoms
- Management testing to direct therapy of an established condition, which may include preoperative or
 postoperative imaging, or imaging performed to evaluate the response to nonsurgical intervention
- **Surveillance** periodic assessment following completion of therapy, or for monitoring known disease that is stable or asymptomatic

- **Indeterminate lesion** focal mass or mass-like finding identified on prior imaging that has not been confidently diagnosed as either benign or malignant based on imaging appearance and/or biopsy
- Cannot be performed or is nondiagnostic applies when the test:
 - Is positive or indeterminate for clinically significant pathology when the information provided about the abnormality by the test is not sufficient to direct subsequent management
 - Is negative when the negative likelihood ratio of the test is both insufficient to confidently exclude the absence of suspected disease and unable to direct subsequent management. This typically applies in scenarios with moderate to high clinical pretest probability with negative testing or low pretest probability with clear evidence for net benefit
 - Has been previously nondiagnostic because of a persistent clinical factor (e.g., body habitus, immobility) that is very likely to make retesting nondiagnostic as well
 - Cannot be performed due to a medical contraindication (e.g., contrast nephrotoxicity, allergy, or in highly radiation sensitive populations such as pediatrics and pregnancy) or reasonable inavailability related to lack of local expertise or service availability.

Statistical terminology

- Confidence interval (CI) range of values which is likely to contain the cited statistic. For example, 92% sensitivity (95% CI, 89%-95%) means that, while the sensitivity was calculated at 92% on the current study, there is a 95% chance that, if a study were to be repeated, the sensitivity on the repeat study would be in the range of 89%-95%.
- **Diagnostic accuracy** ability of a test to discriminate between the target condition and health. Diagnostic accuracy is quantified using sensitivity and specificity, predictive values, and likelihood ratios.
- Hazard ratio odds that an individual in the group with the higher hazard reaches the outcome first.
 Hazard ratio is analogous to odds ratio and is reported most commonly in time-to-event analysis or survival analysis. A hazard ratio of 1 means that the hazard rates of the 2 groups are equivalent. A hazard ratio of greater than 1 or less than 1 means that there are differences in the hazard rates between the 2 groups.
- **Likelihood ratio** ratio of an expected test result (positive or negative) in patients *with* the disease to an expected test result (positive or negative) in patients *without* the disease. Positive likelihood ratios, especially those greater than 10, help rule in a disease (i.e., they substantially raise the post-test probability of the disease, and hence make it very likely and the test very useful in identifying the disease). Negative likelihood ratios, especially those less than 0.1, help rule out a disease (i.e., they substantially decrease the post-test probability of disease, and hence make it very unlikely and the test very useful in excluding the disease).
- Odds ratio odds that an outcome will occur given a particular exposure, compared to the odds of the
 outcome occurring in the absence of that exposure. An odds ratio of 1 means that the exposure does
 not affect the odds of the outcome. An odds ratio greater than 1 means that the exposure is associated
 with higher odds of the outcome. An odds ratio less than 1 means that the exposure is associated with
 lower odds of the outcome.
- **Predictive value** likelihood that a given test result correlates with the presence or absence of disease. Positive predictive value is defined as the number of true positives divided by the number of test positives. Negative predictive value is defined as the number of true negatives divided by the number of test negative patients. Predictive value is dependent on the prevalence of the condition.
- **Pretest probability** probability that a given patient has a disease prior to testing. May be divided into very low (less than 5%), low (less than 20%), moderate (20%-75%), and high (greater than 75%) although these numbers may vary by condition.

- Relative risk probability of an outcome when an exposure is present relative to the probability of the outcome occurring when the exposure is absent. Relative risk is analogous to odds ratio; however, relative risk is calculated by using percentages instead of odds. A relative risk of 1 means that there is no difference in risk between the 2 groups. A relative risk of greater than 1 means that the outcome is more likely to happen in the exposed group compared to the control group. A relative risk less than 1 means that the outcome is less likely to happen in the exposed group compared to the control group.
- **Sensitivity** conditional probability that the test is positive, given that the patient has the disease. Defined as the true positive rate (number of true positives divided by the number of patients with disease). Excellent or high sensitivity is usually greater than 90%.
- **Specificity** conditional probability that the test is negative, given that the patient does not have the disease. Defined as the true negative rate (number of true negatives divided by the number of patients without the disease). Excellent or high specificity is usually greater than 90%.

Clinical Indications

The following section includes indications for which advanced imaging of the abdomen and pelvis is considered medically necessary, along with prerequisite information and supporting evidence where available. Indications, diagnoses, or imaging modalities not specifically addressed are considered not medically necessary. For cancer screening guidelines and management of documented malignancy, please refer to the Oncologic Imaging guidelines.

It is recognized that imaging often detects abnormalities unrelated to the condition being evaluated. Such findings must be considered within the context of the clinical situation when determining whether additional imaging is required.

General Abdominal and Pelvic Indications

Congenital and developmental conditions, not otherwise specified

Advanced imaging is considered medically necessary for diagnosis and management.

IMAGING STUDY

ADULT

- CT abdomen and/or pelvis
- MRI abdomen and/or pelvis

PEDIATRIC

- Ultrasound required for initial evaluation of hepatobiliary and genitourinary anomalies
- Ultrasound recommended for initial evaluation of pancreatic anomalies
- CT abdomen and/or pelvis when additional imaging is needed to guide treatment
- MRI abdomen and/or pelvis when additional imaging is needed to guide treatment
- MRI preferred for evaluation of uterine anomalies
- MRCP preferred for evaluation of biliary and pancreatic duct anomalies

Rationale

A variety of advanced structural and functional imaging modalities may be needed in the diagnosis and management of select intra-abdominal congenital abnormalities. More common anomalies of the gastrointestinal system including pyloric stenosis,

midgut volvulus, Hirschsprung's disease, and small left colon syndrome are usually diagnosed with upper GI series or barium enema. Meckel's scan is useful to diagnose ectopic functioning gastric mucosa, typically in a Meckel's diverticulum (American College of Radiology, 2015, #1) and has moderate to high diagnostic accuracy in patients with subacute unexplained gastrointestinal bleeding. (Spottswood, 2014, #2)·(Irvine, 2017, #3)·(Suh, 2015, #4) Ultrasound is the initial modality for evaluation of congenital hepatobiliary disease. (Dillehay, 2017, #5)· (Yarmish, 2014, #6) Although it requires ionizing radiation, hepatobiliary scintigraphy has high specificity (greater than 98%) and moderate sensitivity (70%) for the diagnosis of biliary atresia with very large positive predictive value sufficient to establish the diagnosis. (Kianifar, 2013, #7) Renal scintigraphy can be useful to establish the diagnosis of congenital anomalies of the kidney and ureter (American College of Radiology, 2017, #8)· (British Nuclear Medicine Society, 2011, #9) or for differential estimation of renal function, especially in the presence of an ectopic, malrotated, or hypoplastic kidney. (British Nuclear Medicine Society, 2011, #9)

Infectious and inflammatory conditions including abscess- not otherwise specified

Advanced imaging is considered medically necessary for diagnosis and management.

IMAGING STUDY

- CT abdomen and/or pelvis
- MRI abdomen and/or pelvis

Rationale

CT or MRI is usually sufficient to evaluate for complications of intra-abdominal infection such as abscess; both modalities are widely available and commonly performed. However, factors such as distorted anatomy, ileus, ascites, and healing wounds can complicate the structural assessment of infection. (Society of Nuclear Medicine, 2004, #10) When diagnostic uncertainty remains following CT and/or MRI, leukocyte scintgraphy may be helpful as an add-on test to further characterize suspected sites of infection such as infected surgical material including vascular grafts, shunts, or abscess. (Society of Nuclear Medicine, 2004, #10) (Panes, 2013, #11)

Trauma, not otherwise specified

Advanced imaging is considered medically necessary for diagnosis and management.

IMAGING STUDY

- CT abdomen and/or pelvis
- MRI abdomen and/or pelvis when CT cannot be performed or is nondiagnostic

Tumor or neoplasm – not otherwise specified

For cancer screening guidelines and management of documented malignancy, please refer to the Oncologic Imaging guidelines.

Advanced imaging is considered medically necessary in EITHER of the following scenarios:

- Evaluation of palpable abdominal or pelvic masses of indeterminate origin
- Characterization of indeterminate lesions arising in the solid abdominal viscera and surrounding anatomic structures

IMAGING STUDY

ADULT

- Ultrasound required for initial evaluation of a palpable pelvic mass in women
- CT abdomen and/or pelvis for all other scenarios, or following nondiagnostic pelvic ultrasound
- MRI abdomen for further characterization of abdominal mass seen on prior imaging, including CT scan

PEDIATRIC

- Ultrasound required for initial evaluation of a palpable pelvic mass
- Ultrasound recommended for initial evaluation of an abdominal mass
- CT abdomen and/or pelvis for initial evaluation of a palpable abdominal mass, or following nondiagnostic ultrasound
- MRI abdomen and/or pelvis for initial evaluation of a palpable abdominal mass, or following nondiagnostic ultrasound

Female Reproductive System and Obstetric Indications

Adenomyosis

Advanced imaging is considered medically necessary for diagnosis and management following nondiagnostic pelvic ultrasound.

IMAGING STUDY

MRI pelvis

Rationale

There is wide clinical agreement and support from multiple clinical guidelines for ultrasound as the initial imaging modality for evaluation of structural pathology within the reproductive organs of the female pelvis(Benacerraf, 2015, #12, Bhosale, 2016, #13, Harris, 2013, #14, 2010, #15) with advanced imaging reserved in select cases as an add-on test to further characterize abnormalities on ultrasound or when ultrasound is nondiagnostic. MRI is the advanced imaging modality of choice due to its superior soft tissue contrast.(Harris, 2013, #14, Brandao, 2013, #16)

Adnexal mass

Advanced imaging is considered medically necessary for diagnosis and management following nondiagnostic pelvic ultrasound.

IMAGING STUDY

MRI pelvis

Rationale

There is wide clinical agreement and support from multiple clinical guidelines for ultrasound as the initial imaging modality for evaluation of structural pathology within the reproductive organs of the female pelvis (Benacerraf, 2015, #12, Bhosale, 2016, #13, Harris, 2013, #14, American Institute of Ultrasound in Medicine, 2010, #15) with advanced imaging reserved in select cases as an add-on test to further characterize abnormalities on ultrasound or when ultrasound is nondiagnostic. MRI is the advanced imaging modality of choice due to its superior soft tissue contrast. (Harris, 2013, #14, Brandao, 2013, #16)

Endometriosis

Advanced imaging is considered medically necessary for diagnosis and management following nondiagnostic pelvic ultrasound.

IMAGING STUDY

MRI pelvis

Rationale

There is wide clinical agreement and support from multiple clinical guidelines for ultrasound as the initial imaging modality for evaluation of structural pathology within the reproductive organs of the female pelvis (Benacerraf, 2015, #12, Bhosale, 2016, #13, Harris, 2013, #14, 2010, #15) with advanced imaging reserved in select cases as an add-on test to further characterize

abnormalities on ultrasound or when ultrasound is nondiagnostic. MRI is the advanced imaging modality of choice due to its superior soft tissue contrast. (Harris, 2013, #14, Brandao, 2013, #16)

A review of 49 studies involving 4807 women was performed to determine whether imaging tests could be used as a replacement for diagnostic surgery or as a triage test to assist in decision making regarding diagnostic surgery. The evaluated modalities included ultrasound, MRI, and CT. While none of the imaging modalities met criteria to replace surgery in making the diagnosis of endometriosis, transvaginal ultrasound did approach the criteria for a triage test for pelvic endometriosis in general. Transvaginal ultrasound met the criteria for a triage test for endometrioma, as well as for deeply infiltrating endometriosis involving the uterosacral ligaments, rectovaginal septum, vaginal wall, pouch of Douglas, and rectosigmoid.(Nisenblat, 2016, #17)

Obstetric indications

Advanced imaging is considered medically necessary for diagnosis and management of ANY of the following:

- Fetal anomalies
- Assessment prior to fetal intervention
- Placental complications
- Complications related to monochorionic twins
- Pelvimetry
- Other obstetrical complications

IMAGING STUDY

- Ultrasound is required for initial evaluation of fetal and placental conditions
- Fetal MRI for indications involving the fetus or placenta, following nondiagnostic ultrasound
- MRI pelvis for pelvimetry or other obstetrical complications

Uterine leiomyomata (fibroids)

Advanced imaging is considered medically necessary following nondiagnostic ultrasound for management prior to a fertility-sparing procedure, with the exception of MR-guided focused ultrasound.

IMAGING STUDY

MRI pelvis

Gastrointestinal Indications

Appendicitis

Advanced imaging is considered medically necessary in EITHER of the following scenarios:

- · Diagnosis of suspected appendicitis
- Perioperative management

IMAGING STUDY

- Nonpregnant adults
 - CT abdomen and pelvis
- Pregnant women

- Ultrasound required for initial evaluation
- o MRI abdomen and pelvis when ultrasound is nondiagnostic
- CT abdomen and pelvis when ultrasound is nondiagnostic and MRI is contraindicated or unavailable

Pediatric patients

- Ultrasound recommended for initial evaluation
- o CT abdomen and/or pelvis when ultrasound cannot be performed or is nondiagnostic
- MRI abdomen and/or pelvis when ultrasound cannot be performed or is nondiagnostic

Rationale

The incidence of acute appendicitis is estimated at 3.4 million cases per year in the U.S. Typical signs and symptoms, including right lower quadrant pain, fever, anorexia, nausea, and vomiting, should lead to surgical consultation. When the diagnosis cannot be made on clinical exam alone, imaging modalities including ultrasound, CT, and MRI may be indicated. Alternative modalities may be considered in pediatric patients and pregnant women due to long-term concerns related to ionizing radiation. (Dahabreh, 2015, #18)

A meta-analysis of 29 studies evaluating the relative accuracies of ultrasound, CT, and MRI for clinically suspected acute appendicitis in children indicated high diagnostic accuracy for all 3 modalities and no statistically significant difference between them.(Zhang, 2017, #19)

A systematic review and meta-analysis found that, with an experienced sonographer, point of care ultrasound is appropriate as the initial imaging test in the evaluation of suspected acute appendicitis in patients of any age. (Matthew Fields, 2017, #20)

In a prospective cohort study of patients age 4 to 30 years to determine predictors for nondiagnostic ultrasound in clinically suspected acute appendicitis, body mass index greater than 85th percentile (odds ratio 4.9 [95% CI, 2.0-12.2]) and older age (odds ratio 1.1 [95% CI, 1.02-1.20]) were found to be statistically significant predictors of nondiagnostic ultrasound. Thus, in younger patients and those not classified as overweight, ultrasound is an appropriate initial study, while other modalities should be considered in older and overweight patients.(Keller, 2017, #21) In pediatric patients with a nondiagnostic ultrasound and clinically suspected appendicitis, MRI was found to have a sensitivity of 90% and specificity of 97.1%, while CT had a sensitivity of 88% and specificity of 98.6%, indicating comparable diagnostic utility of CT and MRI as secondary imaging modalities following ultrasound.(Martin, 2018, #22)

The American College of Radiology indicates that ultrasound is the preferred initial imaging modality in pediatric patients due to lack of ionizing radiation and an accuracy approaching that of CT. In pregnant women, ultrasound is also preferred for initial imaging evaluation, with MRI used as a secondary test when ultrasound is nondiagnostic.(Smith, 2015, #23)

Bowel obstruction

Advanced imaging is considered medically necessary for diagnosis and management.

IMAGING STUDY

- Radiographs required for initial evaluation in pediatric patients
- CT abdomen and/or pelvis when additional imaging is needed to guide treatment
- MRI abdomen and/or pelvis in pediatric patients; MRI abdomen and/or pelvis in adults when CT cannot be performed or is nondiagnostic

Rationale

Abdominal radiography has moderate accuracy (approximately 83%) for the diagnosis of small bowel obstruction and is a useful initial test, especially in radiation-sensitive patients. (Thompson, 2007, #24) CT abdomen and pelvis is a more accurate exam that is less reader-dependent and can provide incremental information over radiographs in differentiating grade, severity, and etiology of small bowel obstructions that may lead to changes in management. (Maung, 2012, #25) In children and younger patients with known or suspected small bowel obstructions or repetitive episodes of obstruction, MRI is indicated as the first-line imaging modality. (Mullan, 2012, #26, Fidler, 2007, #27)

Constipation (Pediatric only)

Advanced imaging is considered medically necessary for evaluation of symptoms persisting 2 or more weeks following nondiagnostic radiographs when **ANY** of the following are present:

- Failure of medical management
- Failure to thrive
- Fever
- Vomiting
- Following barium enema or anal manometry when there is suspicion for ANY of the following:
 - Anal stenosis
 - o Impaction in patients younger than 1 year of age
 - Tight empty rectum

IMAGING STUDY

- CT abdomen and/or pelvis
- MRI abdomen and/or pelvis

Rationale

Constipation is a common problem in children and largely a clinical diagnosis. While a commonly performed practice, there is conflicting evidence that abdominal radiography substantially aids the diagnosis of constipation with at best small likelihood ratios (1-1.2) based on well designed studies. (Reuchlin-Vroklage, 2005, #28) Constipation can have both functional and organic causes. When constipation is associated with red flag features such as failure to thrive, unexplained weight loss, or vomiting, referral to a pediatric gastroenterologist should be considered and additional testing with colonoscopy and/or advanced imaging may be appropriate. (El-Chammas, 2013, #29, Di Lorenzo, 2005, #30)

Diverticulitis

Advanced imaging is considered medically necessary for diagnosis and management.

IMAGING STUDY

• CT abdomen and/or pelvis

Rationale

CT abdomen and pelvis with intravenous contrast should be used to assess for diverticulitis based on recommendations from multiple high quality clinical guidelines. There is a lack of clinical data to support the use of MRI as a first-line modality in the diagnosis of diverticulitis. (Sartelli, 2016, #31)

Enteritis or colitis, not otherwise specified

Includes ischemic, infectious colitis, neutropenic colitis, Henoch-Schonlein purpura, and radiation enteritis, and excludes inflammatory bowel disease.

Advanced imaging is considered medically necessary for diagnosis and management.

IMAGING STUDY

CT abdomen and/or pelvis

Rationale

CT with intravenous and oral contrast is indicated for suspected colonic ischemia to assess the distribution and phase of colitis. The diagnosis of colon ischemia can be suggested based on CT findings, such as bowel wall thickening, edema, or thumbprinting.(Brandt, 2015, #32)

Gastrointestinal bleeding

Also see Vascular Imaging guidelines.

Advanced imaging is considered medically necessary for suspected small bowel source(s) of gastrointestinal bleeding following nondiagnostic endoscopy and colonoscopy.

IMAGING STUDY

- CT abdomen and/or pelvis
- MRI abdomen and/or pelvis when CT cannot be performed or is nondiagnostic

Inflammatory bowel disease (including Crohn's disease and ulcerative colitis)

Advanced imaging is considered medically necessary in **EITHER** of the following scenarios:

- Diagnosis of suspected Crohn's disease following nondiagnostic colonoscopy in ANY of the following clinical scenarios when a patient:
 - Meets criteria for irritable bowel syndrome with a normal colonoscopy and an elevated fecal calprotectin OR C-reactive protein (CRP) level
 - Has concurrent upper gastrointestinal signs or symptoms with a nondiagnostic upper endoscopy
 - Does not meet criteria for irritable bowel syndrome and does not have concurrent upper gastrointestinal signs or symptoms
- Management of new or worsening symptoms to confirm exacerbation or evaluate for complications, including stricture, abscess, toxic megacolon, or fistula

IMAGING STUDY

- CT abdomen and/or pelvis
- MRI abdomen and/or pelvis

Rationale

MRI, CT, and ultrasound may be indicated as an adjunct to endoscopy for diagnosis of colonic inflammatory bowel disease (IBD), which remains the gold standard for diagnosis. MRI and CT have higher sensitivity for examining locations difficult to access by ultrasound. (Panes, 2013, #11)

Small bowel follow through and enteroclysis have high accuracy for mucosal abnormality and are widely available. They are less able to detect extramural complications and are contraindicated in high-grade obstruction and perforation. Radiation exposure is a major limitation. Ultrasound, CT, and MRI have high and comparable diagnostic accuracy at the initial presentation of terminal ileal Crohn's disease. Small bowel follow through and enteroclysis have acceptable accuracy for mucosal disease, but are less accurate for mural disease and extramural complications. (Panes, 2013, #11)

Leukocyte scintigraphy also has the advantage of full gastrointestinal visualization and can detect sites of IBD within the small and large bowel. (Society of Nuclear Medicine, 2004, #10)· (Panes, 2013, #11) Relative to CT/MRI, leukocyte scintigraphy has lower spatial resolution, higher radiation doses, and is less widely available, hence it is typically reserved as an add-on test when CT or MR entergraphy is nondiagnostic.

Calprotectin is a protein released by activated neutrophils, and elevated fecal levels are associated with inflammatory or malignant disease within the colon. (Erbayrak, 2009, #33) Serum C-reactive protein (CRP) is a marker of systemic inflammation. Fecal calprotectin is a sensitive marker for colonic inflammation and is recommended as an option to distinguish

between IBD and irritable bowel syndrome (IBS).(National Institute for Health and Care Excellence, 2013, #34) A recent metaanalysis of 4 (CRP) and 8 (fecal calprotectin) studies found that a CRP level of \leq 0.5 or calprotectin level of \leq 40 μ g/g confers a \leq 1% probability of having IBD.(Menees, 2015, #35)

Upper endoscopy is usually not needed to establish the diagnosis of IBD in the majority of patients, but may be helpful when colonoscopy is nondiagnostic, especially in cases of IBD unspecified or when symptomatic. (Danelius, 2009, #36)

Irritable bowel syndrome (IBS) - see abdominal pain

Perianal fistula/abscess (fistula in ano)

Advanced imaging is considered medically necessary for diagnosis and management when incompletely characterized by physical exam.

IMAGING STUDY

- CT pelvis
- MRI pelvis (preferred)

Rationale

Because the management of perianal fistula is generally surgical, anatomic delineation is important in the management of this condition. Multiple high-quality evidence-based guidelines recommend the use of MRI.^{25,} (Vogel, 2016, #37). (Ong, 2015, #38) Examination under anesthesia (EUA) also plays an important role, and anorectal ultrasound may be a useful initial imaging study where available. CT can identify perianal abscess, but is ionizing and has lower soft tissue contast and diagnostic accuracy when compared to the preferred advanced imaging study, MRI.^{25,} (Ong, 2015, #38)

Hepatobiliary Indications

Biliary tract dilatation or obstruction

Advanced imaging is considered medically necessary for diagnosis and management in **EITHER** of the following scenarios:

- Unexplained biliary tract dilation
- Biochemical evidence of biliary obstruction following nondiagnostic ultrasound

IMAGING STUDY

MRI/MRCP abdomen

Rationale

Dilation of the biliary tract includes a variety of etiologies ranging from benign (such as prior cholecystectomy, choledocholithiasis, inflammatory stricture) to malignant (such as cholangiocarcinoma). Ultrasound offers a non-ionizing, noninvasive view of the intra- and extrahepatic ducts, making it a good initial imaging exam. While ultrasound may be completely diagnostic, MRI/MRCP is a helpful add-on test for biliary duct dilation unexplained by ultrasound, to completely evaluate the biliary ducts when ultrasound is technically insufficient, and in select patients with high pretest likelihood of disease when ultrasound is normal.(Lalani, 2013, #39)· (Greenberg, 2016, #40)· (National Institute for Health and Care Excellence, 2014, #41, Williams, 2017, #42)

Cholecystitis

Advanced imaging is considered medically necessary for diagnosis and management in **EITHER** of the following scenarios:

Acute cholecystitis following nondiagnostic ultrasound

 Complications of acute cholecystitis or cholecystectomy including perforation, abscess, gangrenous or hemorrhagic cholecystitis, gallstone ileus, Mirizzi's syndrome, and bile leak

IMAGING STUDY

- CT abdomen for complications of acute cholecystitis
- MRI abdomen for complications of acute cholecystitis in pediatric patients; MRI abdomen in adults when CT cannot be performed or is nondiagnostic

Note: Advanced imaging not recommended for evaluation of acute uncomplicated cholecystitis.

Rationale

Cholecystitis is a common cause of right upper quadrant pain. Ultrasound has a high diagnostic accuracy for acute cholecystitis and is non-ionizing, widely available, quickly performed and noninvasive, making it an ideal first-line imaging test in suspected cases, an approach endorsed by multiple evidence-based and clinical practice guidelines. (Dillehay, 2017, #5)· (Yarmish, 2014, #6)· (University of Michigan Health System, 2014, #43) Diagnostic testing strategies for suspected acute cholecystitis that start with CT ("initial CT") are also more likely to lead to downstream overutilization, with a recent study finding that initial CT cohorts were 11 times more likely to undergo a second examination than initial ultrasound cohorts. (Ginsburg, 2016, #44)

While ultrasound is usually sufficient for the diagnosis and management of acute uncomplicated cholecystitis, CT has comparable diagnostic accuracy for complicated cholecystitis and can accurately visualize gallbladder distention and wall thickening and identify complications of acute cholecystitis such as gallbladder wall emphysema, abscess formation, and perforation. (European Association for the Study of the Liver (EASL), 2016, #45)

Hepatobiliary scintigraphy is a functional study that may be indicated when a bile leak is suspected post cholecystectomy or as an add-on test following nondiagnostic ultrasound. (Dillehay, 2017, #5) In a recent large (57 studies and 5859 patients) systematic review on the comparative diagnostic accuracy of imaging for acute cholecystitis, hepatobiliary scintigraphy was found to have higher sensitivity (96%; 95% CI, 94%-97%) than ultrasound (81%; 95% CI, 75%-87%) and similar specificity, equating to higher positive and similar negative likelihood ratios and greater overall diagnostic accuracy. (Kiewiet, 2012, #46) However, hepatobiliary scintigraphy is ionizing, less widely available, and takes longer to perform, hence best used as an add-on test following nondiagnostic ultrasound.

Choledocholithiasis

Advanced imaging is considered medically necessary for diagnosis and management following nondiagnostic ultrasound.

IMAGING STUDY

MRI/MRCP abdomen

Rationale

Choledocholithiasis is a common cause of biliary obstruction. Ultrasound has high diagnostic accuracy for acute cholecystitis and is non-ionizing, widely available, quickly performed and noninvasive, making it an ideal first line imaging test in suspected cases, an approach endorsed by multiple evidence-based and clinical practice guidelines. (National Institute for Health and Care Excellence, 2014, #41)· (Williams, 2017, #42)· (European Association for the Study of the Liver (EASL), 2016, #45)

When ultrasound is nondiagnostic, further diagnostic testing with either MRCP or endoscopic ultrasound (EUS) is recommended by multiple high quality evidence-based guidelines, especially in patients with intermediate pretest probability(National Institute for Health and Care Excellence, 2014, #41)· (Williams, 2017, #42)· (European Association for the Study of the Liver (EASL), 2016, #45) Endoscopic ultrasound (EUS) is the gold standard, but MRCP has comparable diagnostic accuracy and is noninvasive. For intermediate pretest probability for choledocholithiasis (10%-50%), the summary sensitivity of EUS is 0.95 compared with 0.93 for MRCP, while summary specificity is 0.97 for EUS compared with 0.96 for MRCP.(Greenberg, 2016, #40)· (Williams, 2017, #42) Diagnostic ERCP has largely been replaced by EUS or MRCP, as the risk of post-ERCP pancreatitis is greater in a patient with normal caliber bile duct and normal bilirubin (odds ratio 3.4 for post-ERCP pancreatitis).(Tenner, 2013, #47)

Diffuse liver disease

For hepatocellular cancer screening in high-risk patients, see the Oncologic Imaging guidelines.

Includes chronic hepatitis, cirrhosis, glycogen storage diseases, hemochromatosis, and Wilson's disease.

Advanced imaging is considered medically necessary in ANY of the following scenarios:

- Evaluation of suspected liver disease based on clinical findings or abnormal liver function tests when ultrasound is nondiagnostic and further evaluation is required
- Evaluation for iron overload in hemochromatosis when chelation therapy or phlebotomy is being considered
- Diagnosis and management of advanced hepatic fibrosis/cirrhosis in patients with established chronic liver disease in EITHER of the following scenarios:
 - Nonalcoholic fatty liver disease (NAFLD) in patients with high risk for cirrhosis due to advanced age, obesity, diabetes, or alanine aminotransferase (ALT) level more than twice the upper limit of normal
 - In other established chronic liver diseases when ultrasound elastography cannot be performed or is nondiagnostic

IMAGING STUDY

- CT abdomen for **EITHER** of the following:
 - Suspected liver disease
 - Iron overload in hemochromatosis when MRI cannot be performed or is nondiagnostic
- MRI abdomen for evaluation of hemochromatosis
- MR elastography for diagnosis and management of advanced hepatic fibrosis/cirrhosis
- Multiparametric MRI (LiverMultiScan) in EITHER of the following scenarios:
 - As an alternative to MR elastography for diagnosis and management of advanced hepatic fibrosis/cirrhosis
 - As an alternative to MRI abdomen for evaluation of hemochromatosis

Rationale

There are many potential causes of diffuse liver damage, including autoimmune disease, infection, hereditary conditions, and toxic or metabolic factors. A common presentation is asymptomatic transaminase elevation detected on routine laboratory testing. Advanced liver disease may manifest as jaundice or aberrations in the synthetic function of the liver.

When imaging is required, ultrasound is the initial study of choice for evaluation of both the liver parenchyma and biliary tree. In a study comparing ultrasonography of alcoholic liver disease to histological correlation, ultrasound had a sensitivity of 95% and specificity of 94%.(Taylor, 1981, #48) Another study comparing histologic findings with ultrasonography for assessment of diffuse parenchymal disease found a sensitivity and specificity of 89% and 93%, respectively.(Joseph, 1991, #49)

Limited data is available comparing accuracy of available cross-sectional imaging modalities. A small trial comparing the ability of ultrasound, CT, and MRI to determine diffuse liver steatosis demonstrated that opposed-phase MRI had the highest correlation with histopathology, compared to T2-weighted MRI with and without fat saturation, CT, and ultrasound for quantification of diffuse liver fat.(Qayyum, 2009, #50) In a multicenter collaborative study evaluating the accuracy, sensitivity, and specificity of these imaging modalities for detecting liver cirrhosis, CT and MRI were not statistically better than ultrasound in receiver operating characteristic analysis.(Kudo, 2008, #51)

Hepatosplenic scintigraphy, typically performed with sulfur colloid, can be used to assess the function of the reticuloendothelial system and may be appropriate when results will determine whether a liver biopsy is performed or whether a potentially hepatotoxic medication is continued.(Royal, 1998, #52)

ELASTOGRAPHY

Liver biopsy is the gold standard for the diagnosis and staging of hepatic fibrosis. However, biopsy has limitations including the potential for sampling error as well as the potential for complications that accompanies any invasive procedure. Biopsy is alsoof limited utility in screening as well as evaluating for response to treatment. Several noninvasive techniques are being explored, including biochemical markers as well as imaging studies. Among the imaging studies being investigated are specific forms of ultrasound-based elastography, magnetic resonance elastography, and MRI with diffusion weighting. Elastography is a method of measuring the stiffness of a given tissue and may be done using ultrasound or magnetic resonance imaging, and may be used to diagnose and stage hepatic fibrosis in patients with chronic liver disease. Elastography is appropriate in patients with non-alcoholic fatty liver disease (NAFLD), alcoholic liver disease, hepatitis B, or hepatitis C. High quality evidence based guidelines from the American Gastroenterological Association Institute recommend MR elastography over vibrationcontrolled transient elastography to evaluate for cirrhosis in high-risk patients with NAFLD (Lim, 2017, #53) and guidelines from the American College of Radiology characterize MR elastography as generally appropriate for diagnosis of hepatic fibrosis.(Horowitz, 2017, #54) Multiple recent systematic reviews have shown high diagnostic accuracy for MR elastography comparable(Xiao, 2017, #55) to marginally greater(Guo, 2015, #56) than ultrasound based elastography depending on technique. One advantage of MR over ultrasound elastography is that the diagnostic accuracy of MR elastography is not compromised by obesity (Singh, 2016, #57) (Singh, 2015, #58) (Su, 2014, #59) In addition, the diagnostic accuracy of MR elastography is similar regardless of the underlying etiology of chronic liver disease.

LiverMultiScan

LiverMultiScan (LMS) is a multiparametric MRI protocol consisting of proton density fat fraction (PDFF), T1, and T2* mapping sequences. A 2018 prospective validation study of 161 patients who had liver biopsies, transient elastography, Enhanced Liver Fibrosis (ELF) test, and contemporaneous LMS found sensitivity of 83% and negative predictive value of 96% for LMS, when evaluating for iron accumulation. In addition, though transient elastography was superior for identification and stratification of liver fibrosis, all three tests were comparable in detecting the presence of clinically significant (moderate or severe) liver fibrosis.(McDonald, 2018, #60) A 2020 prospective study of 145 patients compared quantitative mpMRI, vibration-controlled transient elastography (VCTE), magnetic resonance elastography (MRE), and 2D Shear-Wave elastography (SWE). For nonalcoholic fatty liver disease and nonalcoholic steatohepatitis (NASH), the MR liver fat measurement and controlled-attenuation parameter (CAP) included in LMS had good discriminatory performance while the elastography studies were not as effective.(Imajo, 2021, #61)

Focal liver lesion

For patients with a known primary malignancy, see the Oncologic imaging guidelines.

Advanced imaging is considered medically necessary in **EITHER** of the following scenarios:

- Indeterminate lesions (not biopsied and not fully characterized by prior imaging)
 - Initial evaluation of an indeterminate lesion identified on prior imaging when ANY of the following high-risk features are present:
 - Size larger than 1 cm in diameter
 - Known malignancy
 - Known cirrhosis
 - Hepatitis B or C
 - Alcoholism
 - Sclerosing cholangitis
 - Primary biliary cirrhosis
 - Choledochal cysts
 - Genetic or hereditary disease that predisposes to cirrhosis, including hemochromatosis
 - Anabolic steroid use

- Follow up or surveillance at 3 to 6 months when any of the above risk factors are present, or when the lesion is enhancing, poorly defined, or increasing in size
- Benign lesions (biopsy-proven or fully characterized by imaging)
 - Evaluation of symptoms suggesting a change in size or character
 - o Periodic surveillance of known hepatic adenoma

IMAGING STUDY

- CT abdomen
- MRI abdomen

Note: A simple liver cyst with benign characteristics on ultrasound may not require advanced imaging or surveillance. When multiple lesions are present, the largest and/or most suspicious lesion should be used to determine the appropriateness of advanced imaging and follow up.

Rationale

Common benign liver lesions, such as cysts and hemangiomas, usually have a characteristic appearance on ultrasound; this often eliminates the need for additional evaluation. (Marin, 2009, #62) In the setting of classic imaging findings and low risk for hepatic malignancy, ultrasonography is often sufficient. (Marin, 2009, #62) Otherwise, further evaluation with MRI should be considered. (Lamba, 2014, #63, Belghiti, 2014, #64)

Cavernous hemangiomas are common; autopsy studies have shown that they occur in up to 7% of the population. (Venkatesh, 2014, #65, Garrett, 2013, #66) Hemangiomas appear as a homogenous hyperechoic mass, usually smaller than 3 cm in diameter with acoustic enhancement and sharp margins and are important to identify because they are benign lesions with a characteristic imaging appearance. Confident diagnosis of hemangioma can therefore avoid further biopsy and intervention. Triphasic CT and MRI are usually sufficient to establish the diagnosis. Hemangiomas usually show radiotracer uptake on RBC scintigraphy with high positive likelihood ratios and good interobserver agreement. (Farlow, 1990, #67) (Bradley, 1991, #68) However, this is a historical technique that offers less information about alternative diagnoses and is typically reserved in situations where ultrasound is nondiagnostic and neither triphasic MRI nor CT can be performed. Similarly, sulfur colloid scintigraphy has been used to further characterize suspected focal nodular hyperplasia (Bhoil, 2013, #69), but is rarely performed as both MRI and CT are usually diagnostic.

Simple cysts are also very common in the liver, occurring in about 5% of individuals. Cysts typically show through transmission with no internal echoes and a sharp distant border with edge shadowing on liver ultrasound. (Venkatesh, 2014, #65) Ultrasound is also usually sufficient to characterize small hepatic hemangiomas with typical characteristics in average risk individuals. (European Association for the Study of the Liver (EASL), 2016, #70)

Small hepatic lesions (less than 1 cm) are difficult to characterize and biopsy, but have a high probability of being benign (higher than 80% even in patients with known malignancy), (Marin, 2009, #62) (American Association for the Study of Liver Diseases, 2014, #71) thus close clinical follow up and monitoring for progression may be the most appropriate next step. (Pang, 2016, #72) In an otherwise healthy patient, an incidentally discovered focal liver lesion has an estimated probability of greater than 95% of being benign. (Dietrich, 2013, #73)

Liver lesions are commonly encountered and are commonly identified as incidental findings (incidentalomas) when imaging is performed for other indications. Evidence guiding appropriate use of advanced imaging for diagnosis and surveillance of incidental liver lesions is very limited. Carelon follows the primarily consensus-based approach of the American College of Radiology (ACR) incidental findings committee for hepatic lesions. The committee recommends full characterization of indeterminate lesions measuring more than 1 cm in diameter and in high-risk individuals, including those with a known primary malignancy with a propensity to metastasize to the liver, cirrhosis, chronic hepatitis, sclerosing cholangitis, hemochromatosis, alcoholism, and genetic or hereditary dispositions to cirrhosis. (Pang, 2016, #72)

In terms of appropriate follow up, the American Association for the Study of Liver Diseases, as part of the The American Board of Internal Medicine initiative, recommends that clinicians not perform CT or MRI routinely to monitor benign focal liver lesions unless there is a major change in clinical findings or symptoms. (American Association for the Study of Liver Diseases, 2014, #71) Benign hepatic neoplasms are usually managed conservatively—with the exception of hepatic adenomas due to their risk of rupture, especially when larger than 5 cm. Surveillance of hepatic adenomas in surgical candidates may therefore be appropriate with consensus-based intervals suggested by the European Association for the Study of the Liver (EASL). (European Association for the Study of the Liver (EASL), 2016, #70)

Hepatomegaly

Advanced imaging is considered medically necessary for the diagnosis of clinically suspected or worsening hepatic enlargement when ultrasound is nondiagnostic.

IMAGING STUDY

- CT abdomen
- MRI abdomen in pediatric patients; MRI abdomen in adults when CT cannot be performed or is nondiagnostic

Jaundice

ADULT

Advanced imaging is considered medically necessary for the diagnosis of jaundice when unexplained by liver and biliary function tests.

PEDIATRIC

Advanced imaging is considered medically necessary following nondiagnostic ultrasound, for the diagnosis of jaundice when unexplained by liver and biliary function tests.

IMAGING STUDY

- CT abdomen
- MRI/MRCP abdomen

Rationale

Right upper quadrant ultrasound is the preferred first-line modality in patients with jaundice to evaluate for common bile duct dilation, presence of stones, and to direct any additional testing. If patient has jaundice with a suspected mechanical cause, right upper quadrant pain, or a history of stones, MRI abdomen with and without intravenous contrast and MRCP is second line.(Lalani, 2013, #39)

Primary sclerosing cholangitis

Advanced imaging is considered medically necessary for diagnosis and management.

IMAGING STUDY

MRI/MRCP abdomen

Osseous Indications

Avascular necrosis, bilateral hip

Advanced imaging is considered medically necessary in EITHER of the following scenarios:

- Diagnosis following negative or inconclusive radiographs
- Preoperative planning for osteonecrosis with femoral head collapse

IMAGING STUDY

- MRI pelvis
- CT pelvis when MRI or bone scan not available or contraindicated

Rationale

Avascular necrosis or osteonecrosis is a form of ischemic bone necrosis due to vascular insufficiency. In 60%-75% of cases, avascular necrosis is associated with sickle cell disease, steroid use, alcoholism, chemoradiation, or metabolic bone disease. (Bussieres, 2007, #74) Accurate grading is important for treatment as more advanced stages tend to require surgical intervention whereas medical treatments are favored in earlier stages. When initial radiographs demonstrate avascular necrosis and additional information is needed to guide treatment, MRI without IV contrast is usually appropriate. (Tuite, 2015, #75) Consensus among high-quality evidence-based guidelines also suggests that additional MRI imaging for avascular necrosis is also indicated in high-risk patients when radiographs are normal or inconclusive. Bone scan or CT may be substituted when MRI is not available. (Bussieres, 2007, #74)

Few studies have directly compared the accuracy of MRI and CT in the diagnosis of avascular necrosis, and most of these studies focus on the hip. Those findings are likely applicable to other joints as the disease process is similar. While consensus favors MRI, and MRI has the added benefit of not using ionizing radiation, CT may be more sensitive in detecting subchondral fractures than MRI (MRI had a relative sensitivity of 38% compared to CT for subchondral fracture detection). (Stevens, 2003, #76)

Bone scintigraphy can also identify avascular necrosis that is occult on radiography but is usually recommended when MRI cannot be performed or is nondiagnostic. (Bussieres, 2007, #74). (Murphey, 2016, #77)

Axial spondyloarthropathy

Advanced imaging is considered medically necessary in **ANY** of the following scenarios:

- Diagnosis of nonradiographic spondyloarthropathy (nrSpA) when BOTH of the following are present:
 - o Radiographs which are negative or equivocal for sacroiliitis (Grade 0-2)
 - Inflammatory back pain which has been present for at least 3 months. Inflammatory back pain is defined as back pain with at least FOUR (4) of the following features:
 - Patient is younger than age 40
 - Insidious (gradual) onset
 - Improvement with exercise
 - No improvement with rest
 - Pain at night that improves on getting up
- Baseline imaging prior to therapy when the diagnosis is based on radiographic findings
- Reevaluation in patients who have received at least 3 months of tumor necrosis factor inhibitors without clinical improvement

IMAGING STUDY

MRI pelvis

Rationale

Axial spondyloarthritis includes a group of rare (estimated 0.25% to 1% prevalence) disorders that may be HLA-B27 positive and that manifest with inflammatory changes around the enthesis. Spondyloarthritis includes ankylosing spondylitis, reactive arthritis, psoriatic arthritis, arthropathy associated with inflammatory bowel disease, and undifferentiated spondyloarthritis.

The Assessment of SpondyloArthritis International Society (ASAS) has developed and validated criteria for spondyloarthritis, as well as for their subsets: axial spondyloarthritis and peripheral spondyloarthritis. (Sepriano, 2017, #78) While sacroiliitis is the most common MRI manifestation of axial spondyloarthropathy, bone marrow edema can be seen in the vertebrae as well and characteristic patterns have been described. (Baraliakos, 2016, #79)

There is consensus among guidelines that radiography of the pelvis and/or spine is the preferred imaging modality for initial evaluation of spondyloarthritis. Radiographs of the whole spine are recommended as the first-line imaging modality. (Schueller-Weidekamm, 2014, #80) Plain film X-ray of the sacroiliac joints should be considered for suspected axial spondyloarthritis,

unless the person is likely to have an immature skeleton. (National Institute for Health Care Excellence, 2017, #81) In patients with ankylosing spondylitis (not nonradiographic axial spondyloarthritis), initial conventional radiography of the lumbar and cervical spine is recommended to detect syndesmophytes, which are predictive of development of new syndesmophytes. (Mandl, 2015, #82)

The ASAS criteria for axial spondyloarthritis have a high diagnostic accuracy, sensitivity 82% and specificity 88% based on a systematic review of 9 papers and 5739 patients. (Sepriano, 2017, #78) Patients that do not meet the ASAS criteria are a low pretest probability group unlikely to have axial spondyloarthropathy. The ASAS criteria for axial spondyloarthritis include age < 45 years, back pain of at least 3 months duration, sacroillitis on imaging (either definitive changes on radiography or evidence from MRI) and one characteristic feature, and HLA-B27 positive; or at least 2 characteristic clinical features, which include arthritis, uveitis, dactylitis, psoriasis, Crohn's disease, positive nonsteroidal anti-inflammatory drug response, family history, and positive HLA-B27.

Diagnostic criteria for ASAS are based on MRI of the sacroiliac joints, not the spine. MRI of the spine has a low yield in patients with a negative sacroiliac joint MRI and should not be routinely performed. A retrospective study of 1191 patients under age 45 with chronic lower back pain found sacroiliitis in approximately 7% of patients. Less than 2% of patients with a negative sacroiliac joint MRI had a positive spine MRI, and spine MRI changed management in only 0.16% of cases.(Ez-Zaitouni, 2017, #83) MRI can demonstrate edema of the vertebral body corners (also known as corner inflammatory lesions) and bone marrow edema. A positive MRI spine is defined as 3 or more lesions present on 2 or more slices, but this definition is used primarily for research purposes.(Ez-Zaitouni, 2017, #83)

Consensus among guidelines is that MRI should be obtained in patients with persistent clinical suspicion when radiography is negative or indeterminate. When a diagnosis of axial spondyloarthritis cannot be confirmed and clinical suspicion remains high, a follow up MRI should be considered.(Mandl, 2015, #82) When radiographs are negative and there is suspicion of spondyloarthritis, MRI is mandatory to look for early inflammatory lesions.(Schueller-Weidekamm, 2014, #80) Plain film X-rays, ultrasound, and/or MRI should be considered for other peripheral and axial symptomatic sites.(National Institute for Health Care Excellence, 2017, #81)

A negative/indeterminate radiograph does not satisfy the New York Criteria for Ankylosing Spondylitis (bilateral grade 2–4 or unilateral grade 3–4 sacroiliitis [evidence of erosions, sclerosis, joint space widening, narrowing or ankyloses]) and does not otherwise explain the back pain.

MRI of the sacroiliac joints and/or spine may be used to assess and monitor disease activity in axial spondyloarthritis, providing additional information on top of clinical and biochemical assessments. The decision on when to repeat MRI depends on the clinical circumstances. In general, short tau inversion recovery sequences are sufficient to detect inflammation and the use of contrast medium is not needed.(Mandl, 2015, #82)

Developmental hip dysplasia (Pediatric only)

Advanced imaging is considered medically necessary for preoperative planning.

IMAGING STUDY

• CT pelvis

Osseous tumor

Advanced imaging is considered medically necessary for diagnosis and management.

IMAGING STUDY

- CT pelvis
- MRI pelvis for pediatric patients; MRI pelvis in adults when CT cannot be performed or is nondiagnostic

Note: MRI or radionuclide bone scintigraphy (bone scan) may be more appropriate for detection of skeletal metastases and primary bone tumors.

Osteoid osteoma

Advanced imaging is considered medically necessary following negative or inconclusive hip radiographs.

IMAGING STUDY

CT pelvis

Osteomyelitis

Advanced imaging is considered medically necessary for diagnosis and management.

IMAGING STUDY

- MRI pelvis
- CT pelvis when MRI or bone scan not available or contraindicated

Rationale

Though radiographs often do not show abnormalities associated with osteomyelitis in the first 2 weeks of the infection, they can detect other pathology that may contribute to the patient's symptoms. The information provided by radiographs generally complements that provided by other modalities, so radiographs should be performed even when other imaging is planned.

Radiographs are the appropriate initial imaging study in osteomyelitis because they can demonstrate findings suggestive of the diagnosis, but can also exclude or provide information to suggest other diagnoses. The sensitivity of radiography is reportedly 43%-75% and the specificity is 75%-83%. Abnormal radiographs are helpful, but diagnosis cannot be excluded solely on the basis of negative radiographs. Although sensitivity and specificity of CT are not well established, sensitivity of CT is known to be lower than sensitivity of MRI. For this reason, the utility of CT is limited to specific situations. For example, CT can be used to detect bony sequestra, and has an important role in determining operative therapy. (Pineda, 2006, #84)

Overall, CT has a limited role in the diagnosis of osteomyelitis, and should be used only when imaging is being done to assess the extent of bone destruction, to direct a biopsy, or when MRI is contraindicated. For early detection of osteomyelitis, MRI is superior to other imaging modalities. The sensitivity and specificity for MRI are 78%-90% and 60%-90%, respectively. This compares to sensitivity and specificity of 67% and 50% for CT, and 14%-54% and 68%-70% for radiography.(Hatzenbuehler, 2011, #85)

The American College of Radiology Appropriateness Criteria indicates that for initial imaging evaluation of suspected osteomyelitis, radiographs are rated as "usually appropriate." CT, MRI, and ultrasound are all rated as "usually not appropriate," regardless of whether the studies are to be performed with intravenous contrast. For evaluation of suspected osteomyelitis following radiographs, MRI without and with intravenous contrast is preferred, although radiographs and MRI are both indicated and complementary. MRI without contrast is generally appropriate if contrast is contraindicated, and CT with intravenous contrast is generally appropriate if MRI is contraindicated.

Functional imaging with bone scintigraphy has historically been used to evaluate for osteomyelitis when radiographs are nondiagnostic. Greater accuracy and the lack of ionizing radiation for MRI have largely made scintigraphy an add-on test when MRI cannot be performed or is nondiagnostic(Bussieres, 2007, #74)· (Hatzenbuehler, 2011, #85)· (Beaman, 2017, #86) although bone scintigraphy offers a wider field of view and hence can localize multifocal disease. Similarly, leukocyte scintigraphy is usually not appropriate in the initial evaluation of osteomyelitis(Beaman, 2017, #86), but may play a complementary role to bone scintigraphy in specific scenarios such as multifocal disease.

Pelvic fracture

Includes sacral insufficiency fracture, stress fracture, and traumatic fracture.

Advanced imaging is considered medically necessary in **EITHER** of the following scenarios:

- Diagnosis or management of sacral insufficiency fracture
- Diagnosis or management of stress fracture or traumatic fracture following nondiagnostic pelvic or sacral radiographs

IMAGING STUDY

- Radiographs required prior to advanced imaging for fracture indications other than sacral insufficiency fracture
- CT or MRI pelvis following inconclusive radiographs or initial evaluation of sacral insufficiency fracture

Sacroiliitis, not otherwise specified

Advanced imaging is considered medically necessary for diagnosis and management following pelvic or sacral radiographs in **EITHER** of the following scenarios:

- Condition predisposing to sacroiliitis, such as inflammatory bowel disease, psoriasis, or infection, when radiographs are negative or equivocal for sacroiliitis
- · Radiographs equivocal for sacroiliitis

IMAGING STUDY

- CT pelvis
- MRI pelvis

Septic arthritis

Advanced imaging is considered medically necessary for diagnosis and management.

IMAGING STUDY

- MRI pelvis
- CT pelvis when MRI or bone scan not available or contraindicated

Pancreatic Indications

Pancreatic mass, indeterminate solid

Advanced imaging is considered medically necessary for diagnosis, management, and surveillance.

IMAGING STUDY

- CT abdomen or CT abdomen and pelvis, with pancreatic protocol
- MRI abdomen

Pancreatic mass, indeterminate cystic (IPMN/IPMT)

Note: Common differential considerations for an indeterminate cystic pancreatic mass include intraductal papillary mucinous neoplasm/tumor (IPMN/IPMT), serous/mucinous cystadenoma (SCA/MCA), and pseudocyst.

Note: Indications apply only to asymptomatic cystic pancreatic masses. For symptomatic masses, see relevant symptom-based indication. Unless otherwise specified, enlarging cysts often require endoscopic ultrasound (EUS)/fine needle aspiration (FNA).

ADULT

Advanced imaging is considered medically necessary for diagnosis, management, and surveillance in surgical candidates when EUS/FNA has not been performed or is nondiagnostic in **ANY** of the following scenarios:

- Initial evaluation of an indeterminate mass identified on ultrasound
- Age 80 or greater at the time of diagnosis: every other year for up to 4 years or every other year if enlarging
- Cysts less than 1.5 cm
 - Age less than 65 at diagnosis: every 12 months for up to 9 years from the time of initial diagnosis

- Age 65 to 79 at diagnosis: every 24 months for up to 10 years from the time of initial diagnosis
- Cysts 1.5 cm or greater
 - Every 6-12 months for 2 years then yearly for up to 10 years

PEDIATRIC

Advanced imaging is considered medically necessary for diagnosis, management, and surveillance.

IMAGING STUDY

- CT abdomen or CT abdomen and pelvis
- MRI/MRCP abdomen

Rationale

Cystic pancreatic lesions are commonly encountered incidental findings (incidentalomas). Evidence guiding appropriate use of advanced imaging for diagnosis, management, and surveillance of incidental liver lesions is very limited, However, a primarily consensus-based approach suggested by the American College of Radiology (ACR) incidental findings committee for pancreatic cysts is commonly used in practice. (Megibow, 2017, #87) The common differential for an incidentally discovered cystic pancreatic mass in adults includes intraductal papillary mucinous neoplasm (IPMN), serous cystadenoma (SCA), mucinous cystic neoplasm, and pseudocyst. These lesions have variable malignant potential and are difficult to differentiate, especially when small, making surveillance a common alternative to more invasive management. Frequency of surveillance depends on age, cyst size, interval growth, and the presence of high-risk imaging features such as enhancing nodules, peripheral calcification, or dilation of the main pancreatic duct. Either multiphasic contrast enhanced CT or MRI can be used in the diagnosis, management, and surveillance of cystic pancreatic lesions. While availability and local practice experience impact the modality decision, MRI is non-ionizing and offers greater softer tissue contrast. MRCP may also be helpful in the initial characterization of the cystic pancreatic lesion to define relationship to the main pancreatic duct. (Megibow, 2017, #87) While uncommon, pediatric cystic pancreatic masses are outside the scope of the ACR incidental findings committee recommendations and evidence guiding diagnosis, management, and/or surveillance is very limited.

Pancreatitis

Advanced imaging is considered medically necessary in EITHER of the following scenarios:

- Evaluation of suspected complications due to acute pancreatitis (see pancreatic pseudocyst)
- Recurrent acute pancreatitis of uncertain etiology, defined as more than 2 attacks of acute pancreatitis without established end-stage chronic pancreatitis

Note: Patients with mild acute or uncomplicated pancreatitis usually do not require cross-sectional imaging, aside from ultrasound for identification of gallstones and/or biliary ductal calculi.

IMAGING STUDY

- CT abdomen or CT abdomen and pelvis
- MRI abdomen in pediatric patients; MRI abdomen in adults when CT cannot be performed or is nondiagnostic
- MRCP for recurrent acute pancreatitis to evaluate suspected pancreatic duct anomalies

Rationale

Biochemical testing is more sensitive than CT and often sufficient to make the diagnosis of acute uncomplicated pancreatitis in both children and adults.(Coffey, 2014, #88, Treacy, 2001, #89) Therefore, CT is not indicated and should not be ordered routinely for patients with mild acute pancreatitis.(Quinlan, 2014, #90)

CT should be performed selectively when a broad differential diagnosis that includes acute pancreatitis must be narrowed, especially when biochemical testing is negative or in patients with acute pancreatitis and a suspected local complication (e.g., peritonitis, signs of shock, suggestive ultrasound findings). (Greenberg, 2016, #40) Triphasic CT is accurate for the detection of complications in acute pancreatitis including pseudocysts, pancreatic necrosis, portal vein thrombosis, and visceral artery

pseudoaneurysms. MRI or MRCP may be indicated when a biliary cause for pancreatitis is suspected, especially for recurrent attacks.(Surlin, 2014, #91)

Renal, Adrenal, and Urinary Tract Indications

Adrenal mass, indeterminate

For patients with a known primary malignancy, see the Oncologic imaging guidelines.

ADULT

Advanced imaging is considered medically necessary in **EITHER** of the following scenarios:

- Diagnosis and management of an indeterminate adrenal mass in ANY of the following scenarios:
 - o Greater than 2 cm
 - New or growing within the past 12 months (when prior imaging is available)
 - Biochemical evidence of an adrenal mass
 - Initial evaluation of an indeterminate mass identified on ultrasound
- Surveillance
 - \circ 1 2 cm: Single 12-month follow up
 - Greater than 2 cm unless ANY of the following benign imaging features are present:
 - Absolute wash out greater than 60% or relative wash out greater than 40%
 - Lesion attenuation less than 10 Hounsfield units (HU)
 - Stable over a 12-month interval and less than 4 cm

PEDIATRIC

Advanced imaging is considered medically necessary for diagnosis, management, and surveillance **EITHER** of the following scenarios:

- In neonates, when ultrasound cannot be performed or is nondiagnostic
- In non neonates

IMAGING STUDY

- CT abdomen
- MRI abdomen

Rationale

Incidental adrenal masses, or adrenal incidentalomas, are frequently encountered and represent a diagnostic challenge. Evidence for appropriate surveillance intervals is limited. However, a primarily consensus based approach suggested by the American College of Radiology (ACR) incidental findings committee for adrenal masses is commonly used in practice. (Mayo-Smith, 2017, #92) For indeterminate lesions 2 cm or less without prior imaging or known primary malignacy, 12-month surveillance is suggested. For indeterminate lesions that are enlarging, greater than 2 cm, or present in patients with a known malignancy, further characterization with contrast enhanced CT or MRI or resection is recommended depending on lesion size.

Markers suggestive of malignancy include size greater than 4 cm, irregular margins, nonhomogeneous content, nonuniform enhancement, surrounding tissue invasion or metastasis, attenuation coefficient of 10 Hounsfield units (HU) or greater on noncontrast CT scan, low washout rate on delayed view of contrast CT, and growth over a year.(Mayo-Smith, 2017, #92)

(Song, 2013, #93) No follow up is recommended for lesions with benign features (Fassnacht, 2016, #94, Lee, 2017, #95), specifically lesions with an attenuation of less than 10 HU on non contrast CT. A recent systematic review of 3 studies and 153 patients found the CT less than 10 HU criterion to be 100% sensitive (95% CI, 91%-100%) and 72% specific (95% CI, 60%-82%).(Fassnacht, 2016, #94) Among more than 2300 patients included in published follow-up studies, there is no report of adrenal malignancy in adrenal incidentalomas displaying typical features of adrenocortical adenomas on initial imaging studies.(Fassnacht, 2016, #94)

Pediatric adrenal masses are outside the scope of the ACR incidental findings committee recommendations and evidence guiding diagnosis, management, and/or surveillance is very limited. Ultrasound is used in the initial evaluation of neonatal adrenal masses because it is non-ionizing and does not require sedation.

Bladder or urethral diverticula

Advanced imaging is considered medically necessary for diagnosis and management.

IMAGING STUDY

MRI pelvis

Hematuria

ADULT

Advanced imaging is considered medically necessary for diagnosis and management in **ANY** of the following scenarios:

- Traumatic hematuria
- Macroscopic hematuria
- Microscopic hematuria in **EITHER** of the following scenarios:
 - Symptomatic
 - Asymptomatic in EITHER of the following scenarios:
 - High-risk patients (defined as ANY of the following):
 - Age greater than 59 years
 - More than 30 pack year smoking history
 - More than 25 red blood cells per high powered field (RBC/HPF)
 - History of gross hematuria
 - Low or intermediate risk patients (those not meeting the high risk criteria above) when ALL of the following criteria are met:
 - Persistent and unexplained following repeat urinalysis
 - Negative renal ultrasound
 - Nondiagnostic cystoscopy

PEDIATRIC

Advanced imaging is considered medically necessary for diagnosis and management in **EITHER** of the following scenarios:

- Traumatic hematuria
- Atraumatic hematuria when ultrasound is nondiagnostic

IMAGING STUDY

- CT abdomen and/or pelvis
- MRI abdomen and pelvis (MR urogram) in pediatric patients; MRI abdomen and pelvis (MR urogram) in adults when CT cannot be performed or is nondiagnostic

Rationale

In patients presenting with macroscopic hematuria, the incidence of urological malignancy is 0%-9.3% depending on patient population, with higher rates in male smokers over age 60 and lower rates in patients less than 35.(Lokken, 2012, #96) Advanced imaging is helpful to exclude malignancy in select scenarios and changes management in up 53% of patients.(Pandharipande, 2016, #97)

Incidence of malignacy is lower in patients presenting with asymptomatic atraumatic microscopic hematuria, typically defined as fewer than 3 red blood cells per high powered field (RBC/HPF) on urinalysis. However, once benign causes have been ruled out based on history, physical and laboratory evaluation, the presence of asymptomatic microhematuria should prompt a urologic evaluation which may include advanced imaging. (American College of Radiology, 2014, #98) Examples of benign causes include vigorous exercise, UTI, recent menstruation, known medical renal disease, and recent urological procedures. Advanced imaging is helpful to further characterize macroscopic hematuria. A recent update to a high quality evidence based guideline by the American Urological Association (AUA) recommends that all high risk patients with asymptomatic microhematuria undergo prompt evaluation with CT urography and cystoscopy (strong recommendation based on low quality evidence). Low or intermediate risk patients have a significantly lower pre test likelihood for upper tract malignancy and should first undergo repeat urinalysis and/or cystoscopy and renal ultrasound (moderate (for low risk) and strong (for intermediate risk) recommendation based on low quality evidence). CT urography could be considered in these lower risk patients on a case by case basis if microhematuria remains persistent and unexplained.(Barocas, 2020, #99)

Advanced imaging is helpful to further characterize macroscopic hematuria. Incidence of malignancy is much lower in pediatric patients with hematuria and ultrasound is usually recommended as an initial imaging test because it is non-ionizing and has good diagnostic accuracy for renal stones. (Expert Panel on Pediatric Imaging, 2018, #100)

When advanced imaging is indicated, multiphasic CT urography (without and with intravenous contrast), including sufficient phases to evaluate the renal parenchyma to rule out a renal mass and an excretory phase to evaluate the urothelium of the upper tracts, is the modality of choice because it has the highest sensitivity and specificity for imaging the upper tracts. (American College of Radiology, 2014, #98) MR urography is an option that may be considered as an add on test when contrast enhanced CT is contraindicated. (Barocas, 2020, #99)

Hydronephrosis

Advanced imaging is considered medically necessary to evaluate for obstruction following nondiagnostic ultrasound.

IMAGING STUDY

- CT abdomen and/or pelvis
- MRI abdomen and pelvis (MR urogram) in pediatric patients; MRI abdomen and pelvis (MR urogram) in adult patients when CT cannot be performed or is nondiagnostic

Rationale

Ultrasound, CT, and MRI are all able to detect the presence or absence of hydronephrosis. Ultrasound has moderate diagnostic accuracy, is widely available, and is nonionizing, making it a good initial imaging study when hydronephrosis is suspected. (Wong, 2018, #101) CT and MRI are able to visualize the full course of the ureter and are useful when ultrasound is nondiagnostic. CT is more established, quicker, less motion sensitive, and more commonly performed than MRI (Fritzsche, 2000, #102), although MRI may be useful in pediatric or radiation-sensitive populations. Renal scintigraphy is a functional study that can help differentiate obstructive from nonobstructive hydronephrosis and so determine the clinical significance of suspected hydronephosis, including the impact on renal function and the presence or absence of obstructive uropathy. (American College of Radiology, 2017, #8)· (British Nuclear Medicine Society, 2011, #9)· (Blaufox, 2018, #103)· (Taylor, 2018, #104)

Nephrocalcinosis

Advanced imaging is considered medically necessary for diagnosis and management following nondiagnostic ultrasound.

IMAGING STUDY

CT abdomen

Polycystic kidney disease

Advanced imaging is considered medically necessary for diagnosis and management following nondiagnostic ultrasound, to evaluate total kidney volume AND to assist in decisions on medical therapy.

IMAGING STUDY

- CT abdomen
- MRI abdomen

Pyelonephritis

Advanced imaging is considered medically necessary in EITHER of the following scenarios:

- Acute pyelonephritis in persons with diabetes, history of renal calculi or renal surgery
- Lack of clinical improvement following 72 hours of antibiotic therapy to evaluate for complications such as abscess or another surgical condition
- Diagnosis or management of xanthogranulomatous pyelonephritis

IMAGING STUDY

- CT abdomen
- MRI abdomen when CT cannot be performed or is nondiagnostic

Renal artery stenosis/Renovascular hypertension

See Vascular Imaging guidelines.

Renal masses (includes renal cysts)

For patients with a known primary malignancy, or for renal cancer screening in patients with a genetic predisposition, see the Oncologic imaging guidelines.

See separate indication for Polycystic kidney disease.

ADULT

Advanced imaging is considered medically necessary in patients with a known renal mass and a genetic or medical predisposition to renal cancer or in **ANY** of the following scenarios:

- Diagnosis and management of an indeterminate renal mass in ANY of the following scenarios:
 - o Initial evaluation of an indeterminate mass identified on ultrasound
 - o Growth (more than 3 mm per year) over a 5-year period
 - Mass with at least one suspicious feature (ANY of the following):
 - Thick or irregular cyst wall

- Mural nodule
- Calcification
- Greater than 20 HU on a contrast enhanced CT or between 21 and 69 HU on a noncontrast CT
- Infiltrative or ill defined.
- Management of a solid benign renal mass with new or worsening symptoms
- Surveillance
 - Bosniak IIF: 6 months and 12 months after initial diagnosis, then annually until 5 years from the time of initial diagnosis
 - Solid renal mass suspicious for renal cancer or Bosniak III or IV complex cyst: initial at 6-12 months after initial diagnosis, then annually when part of an active surveillance management strategy

Note: Classification is based on the Bosniak criteria prior to the 2019 update.

PEDIATRIC

Advanced imaging is considered medically necessary for diagnosis, management, and surveillance of an indeterminate renal mass or for management of a solid benign renal mass with active surveillance or with new or worsening symptoms.

Note: Surveillance assumes a dedicated renal protocol CT or MRI has previously been performed for the lesion in question. Renal lesions with benign features do not require further diagnostic imaging.

IMAGING STUDY

- CT abdomen
- MRI abdomen

Note: Simple cysts with benign characteristics on ultrasound do not require advanced imaging or surveillance.

Rationale

When evaluating an incidental renal lesion, previous imaging results should be obtained if available to assess lesion stability. Simple cysts and non calcified renal masses containing macroscopic fat (suggesting angiomyolipomas) are usually fully characterized with ultrasound and/or a noncontrast CT. Benign masses established by imaging or biopsy may require advanced imaging if symptomatic (for instance, due to rupture of microaneurysms within an AML) or as part of active surveillance when growth of the mass will determine whether it is resected.

For an indeterminate cystic renal mass, the Bosniak classification based on results from a CT or MRI with and without contrast is a well-validated tool for management, although evidence for appropriate surveillance intervals is limited. A primarily consensus-based approach has been suggested by the American College of Radiology (ACR) incidental findings committee for adult renal masses and is commonly used in practice.(Herts, 2018, #105) Renal cysts classified Bosniak category I or II require no follow up and include simple cysts, cysts with thin septa and hemorrhagic cysts. Bosniak subcategory IIF cysts are minimally complex and include cysts with nodular calcifications, multiple thickened or thin enhancing septa or hyperdense cysts greater than 3 cm. IIF cysts have a real but low probability of malignancy and may be followed with CT or MRI at 6 months, 12 months, and then yearly for 5 years in patients without limited life expectancy. Cysts categorized Bosniak III or IV are usually treated surgically, but may be followed as part of active surveillance at 6 to 12 months, then yearly for 5 years, especially in patients who are poor surgical candidates or who have limited life expectancy. (Herts, 2018, #105) (Campbell, 2017, #106)

The Bosniak classification requires a CT or MRI with and without contrast to determine the presence or absence of enhancement within the mass. Masses that are indeterminate on ultrasound or that have suspicious features on non-contrast CT should undergo a with and without contrast exam for Bosniak characterization.

Pediatric renal masses vary widely in the malignant potential (Malkan, 2015, #107) and are outside the scope of the ACR incidental findings committee as are patients with established malignancy or a genetic predisposition.

Urinary tract calculi

ADULT

Advanced imaging is considered medically necessary in ANY of the following scenarios:

- Initial evaluation of suspected calculus in patients with no history of nephrolithiasis
- Suspected recurrence* when ANY of the following apply:
 - History of radiolucent calculus
 - History of radiopaque calculus and atypical presentation
 - History of recent radiopaque calculus and typical presentation in EITHER of the following scenarios:
 - In patients less than age 50, following nondiagnostic ultrasound
 - In patients 50 years of age or greater
- Management and follow up of known calculi when ANY of the following apply:
 - Planned percutaneous nephrolithotomy, ureteroscopy, or shock wave lithotripsy, when CT has not been performed within the preceding 30 days
 - Symptomatic patients with known radiolucent calculi
 - Symptomatic patients with radiopaque calculi, following nondiagnostic KUB or ultrasound
 - Asymptomatic patients with persistent hydronephrosis on ultrasound following shock wave lithotripsy or ureteroscopic stone extraction
- Pregnancy
 - o Diagnosis or management following nondiagnostic ultrasound or KUB

PEDIATRIC

Advanced imaging is considered medically necessary following nondiagnostic ultrasound or kidney, ureter, and bladder radiograph.

IMAGING STUDY

- Radiograph or ultrasound required in pregnant women and pediatric patients
- CT abdomen and/or pelvis

Rationale

INITIAL EVALUATION

CT is preferred by the majority of the evidence based guidelines although initial ultrasound evaluation is also appropriate. Ultrasound has been shown to have lower sensitivity but comparable specificity to CT in detecting ureteral stones. It is safe, reproducible, and inexpensive, and can detect upper urinary tract dilatation. (American Urological Association, 2012, #108, European Association of Urology, 2017, #109, Bredemeyer, 2016, #110) CT detects important incidental findings in patients over 80 years of age in 28.9% of cases. (Samim, 2015, #111) CT should be avoided for patients presenting to the emergency

^{*}Recurrence applies when the patient has a prior history of stones but the prior episode has resolved (either the stone is known to have passed based on clinical follow-up, or prior imaging has shown resolution).

department with symptoms consistent with uncomplicated renal colic who are younger than 50 years of age, otherwise healthy, and with known histories of kidney stones or ureterolithiasis. (Abrahamian, 2013, #112)

MANAGEMENT

In a randomized controlled trial, 2500 nonobese adult patients with suspected nephrolithiasis (without a solitary kidney or dialysis dependence) presenting in the emergency department were randomized to initial ultrasound vs CT. No difference was found between the 2 groups in the rates of clinically significant alternative diagnoses, hospitalizations, return emergency department visits, or diagnostic accuracy. (Smith-Bindman, 2014, #113) Use of CT prior to percutaneous nephrolithotomy (PCNL) is a strong recommendation based on low quality evidence from the American Urological Association (AUA). (American Urological Association, 2016, #114) The AUA also makes a conditional recommendation based on low quality evidence for the use of CT to optimize patient selection for shock wave lithotripsy (SWL) instead of ureteroscopy (American Urological Association, 2016, #57) and both approaches are supported by the European Association of Urology (EAU) in their recommendation to "consider the stone composition before deciding on the method of removal". (European Association of Urology, 2015, #115) Post-procedure, the presence of residual known radiopaque calculi in symptomatic patients can often be initially evaluated with radiography and/or ultrasound as suggested by AUA algorithms. (European Association of Urology, 2015, #115)

As ultrasound has moderate-to-high diagnostic accuracy for nephrolithiasis and is non-ionizing, it is the initial modality of choice in radiation-sensitive populations including in pediatrics and pregnancy. (European Association of Urology, 2015, #115)

Splenic Indications

Splenic mass, benign

Advanced imaging is considered medically necessary for management following nondiagnostic ultrasound or rapid growth.

IMAGING STUDY

- CT abdomen
- MRI abdomen

Splenic mass, indeterminate

For patients with a known primary malignancy, see the Oncologic imaging guidelines.

Advanced imaging is considered medically necessary in ANY of the following scenarios:

- Initial evaluation of an indeterminate mass identified on ultrasound
- Enlarging over time
- Features suspicious for malignancy (ANY of the following):
 - Heterogenous enhancement
 - Irregular margins
 - Necrosis
 - Multiple lesions
 - Extension beyond the margin of the spleen
- Surveillance: every 6 months for up to 1 year

IMAGING STUDY

CT abdomen

MRI abdomen

Rationale

Guidelines from the American College of Radiology incidental findings committee on splenic and nodal findings recommend further evaluation with advanced imaging or biopsy when splenic masses with suspicious features are identified in patients with a known malignancy or in patients without a known primary but with suspicious features. For patients with an incidentally discovered splenic mass without a known primary and indeterminate features, follow up imaging at 6 and 12 months is recommended. Indeterminate splenic masses that have been stable for at least a year do not typically require imaging follow up.(Heller, 2013, #116)

Splenomegaly

Advanced imaging is considered medically necessary for clinically suspected or worsening splenic enlargement following nondiagnostic ultrasound.

IMAGING STUDY

- CT abdomen
- MRI abdomen in pediatric patients; MRI abdomen in adults when CT cannot be performed or is nondiagnostic

Miscellaneous Conditions

Hemoperitoneum

Advanced imaging is considered medically necessary for diagnosis and management.

IMAGING STUDY

CT abdomen and/or pelvis

Hernia

Includes femoral, internal, inguinal, Spigelian, ventral, and incisional hernia.

Advanced imaging is considered medically necessary in **EITHER** of the following scenarios:

- Suspected complications
- Presurgical planning

IMAGING STUDY

- Ultrasound required for initial evaluation in pediatric patients
- CT abdomen and/or pelvis
- MRI abdomen and/or pelvis for pediatric patients; MRI abdomen and/or pelvis in adults when CT cannot be performed or is nondiagnostic

Rationale

CT detects occult hernias in approximately 11% of cases and assists in the differential diagnosis of hernia vs other abdominal wall mass. It is useful in surgical planning to define the abdominal wall anatomy in nonmidline hernias such as those on the flanks, suprapubic or subxiphoid regions, and to identify posterior abdominal wall defects. (Earle, 2016, #117)

MRI is favored for groin hernias when ultrasound is nondiagnostic. Sensitivity and specificity for MRI are 94.5% and 96.3%, respectively, vs 83% and 67%-83%, respectively, for CT.(Simons, 2009, #118)

Lymphadenopathy

For patients with a known primary malignancy, see the Oncologic imaging guidelines.

Advanced imaging is considered medically necessary in **ANY** of the following scenarios:

- Diagnosis
 - o In patients with clinical or laboratory findings suggestive of a lymphoproliferative disorder
- Management of lymphadenopathy with suspicious features* when **EITHER** of the following apply:
 - Enlarging over time
 - Clinical or laboratory findings suggestive of a lymphoproliferative disorder
- Surveillance of lymphadenopathy with suspicious features:
 - o 3 months and 12 months after initial diagnosis

IMAGING STUDY

- CT abdomen and/or pelvis
- MRI abdomen and/or pelvis when CT is cannot be performed or is nondiagnostic

Note: MRI may be useful to differentiate enlarged lymph nodes from vascular structures following unenhanced CT scan.

*Note: Suspicious features are defined as ANY of the following:

- Greater than 1 cm in short axis diameter
- Necrosis
- Hypervascularity
- Abnormal morphology including loss of the fatty hilum and thickened cortex
- Cluster of lymph nodes

Rationale

Lymphadenopathy can be due to reactive, infectious, inflammatory or lymphoproliferative etiologies. Guidelines from the American College of Radiology incidental findings committee on splenic and nodal findings recommend further evaluation with advanced imaging or biopsy when lymph nodes with suspicious features are identified in patients with a history of malignancy or when lymphoproliferative disorder is suspected. When clinical evaluation suggests a benign cause for lymphadenopathy, 3-month follow-up CT or MRI is recommended and no follow up is recommended if the nodes have been stable over a 12-month duration.(Heller, 2013, #116)

Pelvic floor disorders associated with urinary or bowel incontinence

Advanced imaging is considered medically necessary for diagnosis and management.

IMAGING STUDY

- MRI pelvis
- Dynamic MRI may be of benefit in some clinical scenarios

Retroperitoneal conditions

Advanced imaging is considered medically necessary for diagnosis and management of **ANY** of the following retroperitoneal conditions:

- Fibrosis
- Inflammation
- Bleeding
- Mass

IMAGING STUDY

- CT abdomen and/or pelvis
- MRI abdomen and/or pelvis for pediatric patients; MRI abdomen and/or pelvis in adults when CT cannot be performed or is nondiagnostic

Sports hernia (athletic pubalgia)

Advanced imaging is considered medically necessary when ALL of the following criteria are met:

- Pain is insidious, progressive, and worsens with Valsalva or movement
- No detectable inguinal or ventral hernia on exam
- Pain has persisted for least 6 weeks
- Radiographs are nondiagnostic
- Symptoms have not improved following at least 6 weeks of conservative therapy
- · Patient is a surgical candidate

IMAGING STUDY

MRI pelvis

Rationale

Athletic pubalgia is a term used to describe chronic groin pain which is of insidious onset and occurs with exertion. Though its incidence in female patients is increasing, the diagnosis predominantly occurs in males. It is uncertain whether this is due to differences in the intensity of exercise in the affected patients, or differences in the anatomy which may reduce the susceptibility of female patients to this condition.(Robinson, 2011, #119)

Conventional radiographs are generally the initial imaging modality in the evaluation of groin pain. Radiographs can identify or exclude conditions such as tumor, fracture, osteoarthritis, or advanced avascular necrosis, that may account for the patient's symptoms. Though no single modality has demonstrated adequate sensitivity and specificity for making the diagnosis, specific findings associated with the diagnosis have been described on both MRI and dynamic ultrasonography. (Suarez, 2013, #120)

Initial treatment is nonsurgical and may include anti-inflammatory medication, rest, heat or ice, and deep massage. Physical therapy may also be helpful. Surgical management should be considered in patients who do not respond to a 6- to 8-week course of nonsurgical management and after other causes for the pain have been excluded via history and physical examination as well as imaging studies.(Farber, 2007, #121)

Perioperative evaluation, not otherwise specified

Transplant-related imaging

Advanced imaging is considered medically necessary in the following scenarios:

- For living donors, a single pre-transplant evaluation
- For patients on the transplant waiting list for liver transplantation, annual surveillance
- Evaluation of suspected post-transplant complications

Note: For patients on the transplant list but who have not undergone transplantation and who have a change in clinical condition, please refer to the applicable sign- or symptom-based indication.

IMAGING STUDY

- CT abdomen or CT abdomen/pelvis
- MRI abdomen as an alternative to CT abdomen for surveillance in patients on the waiting list for liver transplantation

Nonspecific Signs and Symptoms

Abdominal and/or pelvic pain, undifferentiated

Note: Nonacute abdominal pain is defined as pain that has occurred at least 1 day per week for at least 90 days. Abdominal pain should be evaluated in the context of a differential diagnosis based on findings from history, physical exam, and relevant lab results. Usually, the appropriateness of imaging for abdominal pain should be evaluated based on the most likely diagnosis. This guideline applies to patients with atraumatic abdominal pain without a clear source when a most likely diagnosis cannot be established or is uncertain (undifferentiated).

ADULT

Advanced imaging is considered medically necessary in **EITHER** of the following scenarios:

- Acute abdominal pain associated with clinical findings of a surgical abdomen, including severe
 undifferentiated abdominal pain or guarding or that remains unexplained after ALL of the following:
 - History
 - Physical exam
 - Lab results where relevant
 - Prior imaging where available
 - Ultrasound if the pain localizes to the right upper quadrant (abdominal ultrasound) or female pelvis (pelvic ultrasound)
- Nonacute abdominal pain that remains unexplained after ALL of the following:
 - History
 - Physical exam
 - Lab results where relevant
 - o Prior imaging where available
 - Ultrasound if the pain is localized to the right upper quadrant (abdominal ultrasound) or female pelvis (pelvic ultrasound)
 - Upper endoscopy if the pain is epigastric unless associated with elevated inflammatory markers (leukocytosis, C-reactive protein [CRP])

 Colonoscopy if the pain is associated with defecation and a change in the form and frequency of stools (i.e., irritable bowel syndrome)

PEDIATRIC

Advanced imaging is considered medically necessary for diagnosis in ANY of the following scenarios:

- Acute abdominal pain associated with clinical findings of a surgical abdomen, including severe
 undifferentiated abdominal pain or guarding or that remains unexplained after ALL of the following:
 - History
 - Physical exam
 - Lab results where relevant
 - Prior imaging where available
 - Abdominal or pelvic ultrasound
- Chronic or recurrent pelvic pain following nondiagnostic ultrasound
- Chronic or recurrent abdominal pain following nondiagnostic ultrasound when ANY of the following red flag signs are present:
 - Chronic severe diarrhea (at least 3 watery stools per day for more than 2 weeks)
 - Deceleration of linear growth
 - Fever of unknown origin
 - Gastrointestinal bleeding
 - History of a genetic or congenital syndrome
 - Immunocompromised
 - Involuntary weight loss
 - o Persistent focal abdominal pain, especially right upper or right lower quadrant
 - o Persistent vomiting
 - Elevated inflammatory markers (leukocytosis, C-reactive protein [CRP])

IMAGING STUDY

- CT abdomen for upper quadrant (right or left) and epigastric pain
- CT abdomen and/or pelvis for lower quadrant (right or left) and generalized abdominal pain
- CT pelvis for pelvic pain
- MRI pelvis for pelvic pain
- MRI abdomen in pediatric patients; MRI abdomen in adults when CT cannot be performed or is nondiagnostic

Rationale

ACUTE ABDOMINAL PAIN

In adult patients with unexplained, nonspecific atraumatic abdominal pain, CT has high diagnostic accuracy in the evaluation of acute abdominal pain and is recommended by multiple guidelines when the pain is unexplained by clinical and, where

relevant, laboratory evaluation. (Sartelli, 2013, #122) (Gans, 2015, #123) CT is the also the single best diagnostic adjunct to augment the clinical exam. While combinations of clinical and laboratory findings offer modest positive (3.2) and negative (.69) likelihood ratios for the diagnosis of acute abdominal pain, the addition of CT improves these ratios to 9.2 and 0.09, effectively ruling in and out acute disease where positive and negative. (Gerhardt, 2005, #124) Two exceptions to the initial use of CT are for pain localizing to the right upper quadrant and female pelvis given the high diagnostic accuracy of ultrasound for hepatobiliary and uterine/adnexal disease. (Bhosale, 2016, #13)

In pediatric patients with unexplained, nonspecific atraumatic abdominal pain, CT is not always necessary. (American Academy of Pediatrics, June 20 2018, #125) Ultrasound is suggested as an initial imaging modality (Reust, 2016, #126), as it is non-ionizing and can establish the diagnosis for several causes of pain including appendicitis, cholecystitis, hernia, hemorrhagic cysts, and testicular or ovarian torsion. CT is useful when ultrasound is nondiagnostic or unavailable and in emergent situations where the use of ultrasound may delay the diagnosis (such as peritonitis).

CHRONIC ABDOMINAL PAIN

CT is often used in adults with chronic atraumatic abdominal pain, but the utility of CT and its position in the diagnostic testing strategy vary by location of the pain. Ultrasound is recommended in the initial evaluation of right upper quadrant pain, since the pain is often hepatobiliary in origin(Lalani, 2013, #39) (see also hepatobiliary indications). For right/left lower quadrant pain, ultrasound has lower diagnostic accuracy and is more operator dependent, thus CT is commonly recommended as a first line imaging test.(Dahabreh, 2015, #18)· (Howell, 2010, #127)· (Smith MP, 2015, #128) Patients with organic epigastric pain not better accounted for by pancreatitis, diverticulitis, hepatobiliary or other more specific indications are more likely to have a gastrointestinal than a hepatobiliary etiology for their symptoms(Yamamoto, 1997, #129), typically dyspepsia and an ulcer. Endoscopy, not CT, is usually the initial imaging test in patients with dyspepsia who have failed empiric therapy or who have red flag features.(de Jong, 2019, #130) Advanced imaging may be helpful in patients with significantly elevated WBC or ESR, as the positive predictive value for intra-abdominal pathology is high.(Gans, 2015, #131) Advanced imaging is not typically needed in patients who meet the Rome 3 or 4 criteria for irritable bowel syndrome (IBS). While the pretest probability for structural disease in patients with IBS is comparable to the population average(O'Connor, 2012, #132), additional investigations may be required in the presence of red flags, such as age over 50, unintended weight loss, or persistent diarrhea. Colonoscopy, not routine CT or MRI, is the imaging test of choice.(Moayyedi, 2017, #133)

The American Academy of Pediatrics notes that functional abdominal pain generally can be diagnosed correctly without the need for additional diagnostic tests if the patient is 4 to 18 years of age with chronic abdominal pain when there are no alarm symptoms or signs, the physical examination is normal, and the stool sample tests are negative for occult blood. (2005, #134) However, the American Academy of Pediatrics also recommends further evaluation in a subgroup of patients with alarm or red flag features which include involuntary weight loss, deceleration of linear growth, gastrointestinal blood loss, significant vomiting, chronic severe diarrhea, persistent right upper or right lower quadrant pain, unexplained fever, family history of inflammatory bowel disease, or abnormal or unexplained physical findings. These features indicate a need to perform diagnostic testing for specific anatomic, infectious, inflammatory, or metabolic etiologies on the basis of specific symptoms. (2005, #134) Significant focal tenderness is also an alarm feature. Advanced imaging may be indicated in the presence of red flag features associated with chronic or recurrent pediatric abdominal pain.

Fever of unknown origin

Advanced imaging is considered medically necessary in EITHER of the following scenarios:

- Fever of duration greater than 3 weeks which is unexplained following a standard diagnostic evaluation to identify the source
- Unexplained fever in immunocompromised patient

IMAGING STUDY

• CT abdomen and/or pelvis

Lower extremity edema

Advanced imaging is considered medically necessary for evaluation when diffuse and unexplained by venous ultrasound.

IMAGING STUDY

• CT abdomen and/or pelvis

 MRI abdomen and/or pelvis in pediatric patients; MRI abdomen and/or pelvis in adults when CT cannot be performed or is nondiagnostic

Rationale

Diffuse swelling of the lower extremities has a variety of causes, including lymphedema due to chronic lymphatic insufficiency. (Szuba, 2003, #135) Lymphoscintigraphy can help to determine whether obstruction to lymphatic flow is responsible for diffuse swelling and help to direct both medical and surgical interventions. (Szuba, 2003, #135, Kalawat, 2012, #136)

Weight loss

Also see Chest Imaging guidelines.

Advanced imaging is considered medically necessary for evaluation of unintentional weight loss exceeding 5% of body weight within a 12-month interval in **EITHER** of the following scenarios:

- Persistence following a negative comprehensive clinical evaluation (including a history and physical examination, age-appropriate cancer screening, chest radiography, and initial laboratory evaluation) after a period of observation
- Abnormal findings suggestive of malignancy on history, physical exam, imaging, or laboratory evaluation

IMAGING STUDY

CT abdomen and/or pelvis

Rationale

Persistent unintentional weight loss is defined as a substantive weight loss over a period of 6 to 12 months. (Gaddey, 2014, #137) Weight loss is not uncommon in elderly patients and is typically related to one of the 7 Ds: dementia, dentition, depression, diarrhea, drugs, functional dysfunction, or dysphagia. When unintentional weight loss remains unexplained, it may be due to the 8th D: acute or chronic disease. (Gaddey, 2014, #137)

The primary purpose of advanced imaging in the evaluation of unexplained unintentional weight loss is to exclude an occult malignancy not detected by initial clinical evaluation and testing, usually in patients with abnormalities on baseline testing. CT screening is of limited value. Instead, diagnostic testing should be directed toward areas of concern based on the history and physical examination. (Stajkovic, 2011, #138) Age-appropriate screening for malignancy (mammogram, pap smear) should also be encouraged. (Wong, 2014, #139)

The most common cause of malignancy among patients with unintentional weight loss is of gastrointestinal primary (47%), and gastrointestinal causes account for 45% of nonmalignant organic etiologies. (Bosch, 2017, #140) Therefore, endoscopy and/or colonoscopy should be considered for initial evaluation when there is evidence for a gastrointestinal source.

CT with contrast is sensitive for the detection of lymphoma, lung and genitourinary cancers, which are the next most common causes of malignancy in patients with unintentional weight loss.

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Codes

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

CPT/HCPCS

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72192	CT pelvis without contrast
72193	CT pelvis with contrast
72194	CT pelvis without contrast, followed by re-imaging with contrast
72195	MRI pelvis without contrast

72196	MRI pelvis with contrast
72197	MRI pelvis without contrast, followed by re-imaging with contrast
74150	CT abdomen without contrast
74160	CT abdomen with contrast
74170	CT abdomen without contrast, followed by re-imaging with contrast
74176	CT abdomen and pelvis without contrast
74177	CT abdomen and pelvis with contrast
74178	CT abdomen and pelvis without contrast in one or both body regions, followed by re-imaging with contrast
74181	MRI abdomen without contrast
74182	MRI abdomen with contrast
74183	MRI abdomen without contrast, followed by re-imaging with contrast
74712	MRI fetal, including placental and maternal pelvic imaging when performed, single or first gestation
74713	MRI fetal, including placental and maternal pelvic imaging when performed, each additional gestation (List separately in addition to code for primary procedure)
76391	Magnetic resonance (e.g., vibration) elastography
S8037	Magnetic resonance cholangiopancreatography (mrcp)
0648T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session
0649T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)

ICD-10 Diagnosis

Refer to the ICD-10 CM manual

History

Status	Review Date	Effective Date	Action
Revised	05/26/2021	03/13/2022	Independent Multispecialty Physician Panel (IMPP) review. Revised the following indications: Uterine artery embolization procedures, Diffuse liver disease, Jaundice, Sacroiliitis, Pancreatic mass, Pancreatitis, Hematuria, Polycystic kidney disease, Renal mass, and Urinary tract calculi. Removed Intussusception and Azotemia. Added CPT codes 0648T and 0649T.
Revised	05/26/2021	11//07/2021	IMPP review. Added Transplant-related imaging.
Revised	-	03/14/2021	Added HCPCS code S8037.
Revised	06/10/2019	02/09/2020	IMPPreview. Revised the following indications: Enteritis or colitis, Foreign body (pediatric only), GI bleeding, Henoch-Schonlein purpura, Inflammatory bowel disease, Intussusception (pediatric only), Ischemic bowel, Hematoma or hemorrhage, Perianal fistula/abscess, Ascites, Biliary tract dilatation or obstruction, Cholecystitis, Choledocholithiasis, Diffuse liver disease, Focal liver lesion, Hepatomegaly, Jaundice, Pancreatic mass, Adrenal mass indeterminate, Hematuria, Renal mass, Urinary tract calculi, Splenic mass benign, Splenic mass indeterminate, Splenomegaly, Adrenal hemorrhage, Adrenal mass, Lymphadenopathy, Splenic hematoma, Undescended testicle,

Status	Review Date	Effective Date	Action
			Abdominal pain, Lower extremity edema, and Pelvic pain. Moved Azotemia and Adrenal mass to Renal/adrenal indications, Splenomegaly to Splenic indications, and Prostate cancer to Oncologic imaging. Added CPT code 76391.
Restructured	09/12/2018	01/01/2019	IMPP review. Advanced Imaging guidelines redesigned and reorganized to a condition-based structure. Incorporated AIM guidelines for pediatric imaging.
Revised	07/11/2018	03/09/2019	IMPP review. Renamed the Administrative Guidelines to "General Clinical Guideline." Retitled Pretest Requirements to "Clinical Appropriateness Framework" to summarize the components of a decision to pursue diagnostic testing. Revised to expand applicability beyond diagnostic imaging, retitled Ordering of Multiple Studies to "Ordering of Multiple Diagnostic or Therapeutic Interventions" and replaced imaging-specific terms with "diagnostic or therapeutic intervention." Repeated Imaging split into two subsections, "repeat diagnostic testing" and "repeat therapeutic intervention."
Revised	03/01/2018	10/29/2018	IMPP review. Lowered threshold for unexplained weight loss and more explicitly defined preliminary work up in CT abdomen/CT pelvis/CT abdomen and pelvis. Added hemochromatosis as an indication for MRI abdomen in pediatric patients.
Created	-	03/30/2005	Original effective date.