American College of Radiology
ACR Appropriateness Criteria®
Fibroids

Variant 1:   **Clinically suspected fibroids. Initial imaging.**

Procedure	Appropriateness Category	Relative Radiation Level
US duplex Doppler pelvis	Usually Appropriate	O
US pelvis transabdominal	Usually Appropriate	O
US pelvis transvaginal	Usually Appropriate	O
MRI pelvis without and with IV contrast	May Be Appropriate	O
MRI pelvis without IV contrast	May Be Appropriate	O
CT pelvis with IV contrast	Usually Not Appropriate	☢☢☢
CT pelvis without IV contrast	Usually Not Appropriate	☢☢☢
CT pelvis without and with IV contrast	Usually Not Appropriate	☢☢☢☢

Variant 2:   **Known fibroids. Treatment planning. Initial imaging.**

Procedure	Appropriateness Category	Relative Radiation Level
US duplex Doppler pelvis	Usually Appropriate	O
US pelvis transabdominal	Usually Appropriate	O
US pelvis transvaginal	Usually Appropriate	O
MRI pelvis without and with IV contrast	Usually Appropriate	O
MRI pelvis without IV contrast	May Be Appropriate	O
CT pelvis with IV contrast	Usually Not Appropriate	☢☢☢
CT pelvis without IV contrast	Usually Not Appropriate	☢☢☢
CT pelvis without and with IV contrast	Usually Not Appropriate	☢☢☢☢

Variant 3:   **Known fibroids. Surveillance or posttreatment imaging.**

Procedure	Appropriateness Category	Relative Radiation Level
US duplex Doppler pelvis	Usually Appropriate	O
US pelvis transabdominal	Usually Appropriate	O
US pelvis transvaginal	Usually Appropriate	O
MRI pelvis without and with IV contrast	Usually Appropriate	O
MRI pelvis without IV contrast	May Be Appropriate	O
CT pelvis with IV contrast	May Be Appropriate	☢☢☢
CT pelvis without IV contrast	Usually Not Appropriate	☢☢☢
CT pelvis without and with IV contrast	Usually Not Appropriate	☢☢☢☢

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Summary of Literature Review

Introduction/Background

Uterine fibroids (leiomyomas or myomas) are the most common neoplasm of the uterus. They are composed of benign smooth muscle cells embedded in an extracellular matrix of collagen, fibronectin, and proteoglycan [1]. The prevalence of fibroids varies with race. Black women have an estimated incidence of fibroids by age 50 exceeding 80%, whereas White women have an incidence approaching 70% [2]. Although incompletely understood, fibroid etiology is multifactorial. A combination of genetic alterations and endocrine, autocrine, environmental, and other factors such as race, age, parity, and body mass index all play a role in fibroid development. Black women are more likely to develop clinically significant disease at an earlier age and are subject to racial disparities, including higher rates of surgical intervention when compared with medical therapy, as well as lower rates of minimally invasive approaches [3-6].

Fibroid-associated symptoms peak in the perimenopausal years and decline after menopause. Menorrhagia is the most frequent symptom and often results in iron deficiency anemia. Other common symptoms include dysmenorrhea, pelvic pain and pressure, urinary urgency and frequency, and constipation. Fibroids may also impair fertility and/or cause obstetric complications [7]. Despite the high prevalence and protean symptoms, there are few randomized trials to guide therapy. Patient preferences and symptom severity help inform treatment choice with options ranging from medical therapy to surgery. Hysterectomy is curative. One-half to one-third of the approximately 600,000 hysterectomies performed annually in the United States are for symptomatic fibroids [1,4]. Uterine sparing therapies include medical therapy (eg, GnRH agonists, levonorgestrel-releasing intrauterine devices, contraceptive steroid hormones, and tranexamic acid), myomectomy, endometrial ablation, uterine fibroid embolization (UFE), MR-guided focused ultrasound (MRgFUS), and laparoscopic radiofrequency ablation. Of these, myomectomy and UFE are the most common, and in a recent multicenter, randomized, open-label trial comparing myomectomy to UFE, both therapies resulted in equivalent symptomatic improvement at 2 years [8].

In addition to an individual woman's symptoms, the economic burden of symptomatic fibroids to society is large. Total estimated societal costs range from $5.9 to $34.4 billion annually, with lost work hours accounting for the largest proportion of these costs [7].

Special Imaging Considerations

Saline infusion sonohysterography (SIS), a minimally invasive procedure distending the endometrial cavity with saline, enables better delineation between endometrial pathologies (polyps, hyperplasia, synechiae, etc) and submucosal fibroids. Studies have shown an overall good agreement (kappa 0.80) between 3-D SIS and diagnostic hysteroscopy to classify submucosal fibroids [9,10]. SIS has also been shown to accurately depict the percentage intracavitary component of submucosal fibroids, a finding that often has treatment implications [11,12].

Three-dimensional transvaginal ultrasound (3-D TVUS) is a reconstruction of the US volumetric data into high-resolution multiplanar imaging, including real-time surface rendered images [13]. In initial assessment, 3-D US has been used along with 2-D US for uterine pathologies, mostly submucosal fibroids, and endometrial polyps. A study of 139 cases comparing 3-D US against hysteroscopy in diagnosing uterine cavity abnormalities showed a sensitivity and specificity of 87% and 100% in diagnosing submucosal leiomyoma [14]. However, another study showed no significant advantage of 3-D US over 2-D US in estimating intracavitary protrusion of submucosal

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fibroid with a reference standard of hysteroscopy and a moderate interobserver agreement of 3-D US for submucosal fibroid [15].

US elastography/sonoelastography is a technique that measures tissue strain. Strain elastography used with routine TVUS has shown increased diagnostic accuracy in identifying myometrial pathologies (fibroids and adenomyosis) from normal myometrium [16,17]. On sonoelastography, foci of adenomyosis are seen as brighter irregular shaped lesions (because of the presence of endometrial glands and stroma implanted within the myometrium), whereas fibroids are seen as well-delineated dark areas (secondary to stiffer/compressed smooth muscle fibers) [18,19]. Compression sonoelastography is a method of applying gentle compression causing alteration in size and shape of the lesion based on the tissue stiffness, which can be qualitatively (as a color map) or quantitatively recorded. Studies have shown high interobserver and intermethod agreement for the measurement of uterine and fibroid volumes on compression elastography [19] and excellent agreement between elastography-based diagnosis of fibroids and adenomyosis with MRI-based diagnosis [18].

The role of artificial intelligence in imaging fibroids is currently under investigation. There are several studies evaluating machine learning with textural analysis to improve the diagnostic accuracy of differentiating fibroids from sarcomas [20].

Initial Imaging Definition

Initial imaging is defined as imaging at the beginning of the care episode for the medical condition defined by the variant. More than one procedure can be considered usually appropriate in the initial imaging evaluation when:

- There are procedures that are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care)

OR

- There are complementary procedures (ie, more than one procedure is ordered as a set or simultaneously where each procedure provides unique clinical information to effectively manage the patient's care).

Discussion of Procedures by Variant

Variant 1: Clinically suspected fibroids. Initial imaging.

CT Pelvis

There is no relevant literature to support the use of pelvic CT without or with intravenous (IV) contrast as initial imaging modality for clinically suspected fibroids.

MRI Pelvis

MRI excels at identifying and mapping fibroids [21-25]. When MRI is clinically useful, the use of a gadolinium-based IV contrast agent is preferred for identification of fibroid vascularity and other characteristics [26]. Please see the ACR Manual on Contrast Media for additional information [27].

Signal intensity and contrast enhancement allow diagnosis of fibroids to include size, number and location, and assessment of vascularity and to help characterize them as classic, degenerated (hyaline, carneous, hydropic, fatty, cystic, and myxoid), cellular, or atypical [28-30]. Conventional MRI, however, cannot accurately differentiate fibroids from sarcomas, a critical distinction for surgical planning and optimizing outcomes [31-33]. Diffusion-weighted imaging with apparent diffusion coefficient (ADC), especially when incorporated into an MRI algorithm, has shown promising results in distinguishing the two entities [20,34-40]. In a large, case-controlled retrospective study of women with atypical uterine masses, a diagnostic algorithm based on enlarged lymph nodes, peritoneal implants, high diffusion MRI signal, and low ADC values was developed and validated. The resulting algorithm achieved a 98% sensitivity and a 96% specificity in the training set and 83% to 88% sensitivity and 97% to 100% specificity in the validation sets [34]. Machine learning with texture analysis is under investigation and may have the potential to improve diagnostic accuracy [20].

MRI can differentiate fibroids from alternative or comorbid conditions such as adenomyosis and endometriosis that often cause similar symptoms [41,42].

US Pelvis Transabdominal

A combination of transabdominal US (TAUS) and TVUS of the pelvis is the most useful modality in the initial evaluation of suspected uterine fibroid or abnormal uterine bleeding [43-45]. TAUS is often useful in significantly

enlarged fibroid uterus or large subserosal/pedunculated fibroids that may render poor visualization on TVUS because of limited field-of-view from poor acoustic penetration. A potential limitation of TAUS is the poor acoustic window from decompressed urinary bladder, retroverted uterus, large body habitus, and bowel gas [46].

US Pelvis Transvaginal

TVUS provides higher contrast and spatial resolution and should be combined with the TAUS whenever possible to evaluate suspected uterine fibroid [46,47]. TVUS has a reported sensitivity of 90% to 99% for detecting uterine fibroids and a sensitivity of 90% and specificity of 98% for the diagnosis of submucosal fibroids [43,48,49]. Three-dimensional TAUS and TVUS along with Doppler has shown high accuracy in differentiating uterine fibroids from adenomyosis with a sensitivity, specificity, and negative predictive value of 93%, 96%, and 88% for fibroids and 96%, 93%, and 98% for adenomyosis [50].

In a meta-analysis by Bittencourt et al [51], the pooled sensitivity and specificity of 2-D TVUS with SIS in diagnosing submucosal fibroids was 94% and 81%, respectively. The limitations of TVUS are a limited depth of penetration and a shallow focal length that can limit the evaluation of large or subserosal/pedunculated fibroids.

US Duplex Doppler Pelvis

Although Doppler imaging is labeled under separate imaging procedure per ACR methodology, this document considers it to be a standard component of pelvic US. Color Doppler is routinely used in pelvic US examinations to evaluate internal vascularity of pelvic/uterine findings and to differentiate between vascular and nonvascular tissue [47].

Uterine fibroids show increased peripheral vascular flow on color Doppler imaging [52]. The presence of interface vessels between the uterus and juxtauterine masses ("bridging vessel sign") is an important feature to differentiate subserosal fibroid from extrauterine tumors [53,54]. Duplex color Doppler typically shows high velocity, low resistive index, and low pulsatility index in the uterine arteries of uteri with fibroids than with normal uteri [55,56]. A resistive index <0.7 and pulsatility index <1.2 on spectral Doppler US showed a sensitivity of 93.4% and specificity of 95.6% and diagnostic accuracy of 93.8% in differentiating uterine leiomyoma from adenomyosis [50].

US duplex Doppler evaluation may also help in differentiating submucosal/intracavitary fibroids from endometrial polyps. Visualization of a vascular pedicle on transvaginal color Doppler imaging has a specificity of 95% to 98% and a negative predictive value of 81% to 94% for the detection of endometrial polyps [57,58].

Variant 2: Known fibroids. Treatment planning. Initial imaging.

CT Pelvis

There is no relevant literature to support the use of pelvic CT without or with IV contrast as initial imaging in treatment planning for symptomatic fibroids. CT, however, can better delineate calcified fibroids relative to US and MRI that may have treatment implications.

MRI Pelvis

MRI is superior to US (transabdominal followed by transvaginal) for identifying and mapping fibroids and may alter management in up to 28% of patients [22-25,59-61]. When MRI is clinically useful, the use of a gadolinium-based IV contrast agent is preferred [26]. Please see the ACR Manual on Contrast Media for additional information [27].

Fibroid location, volume, number, T1- and T2-weighted signal intensity, and enhancement provide important pretreatment information [25,62-65]. Intracavitary fibroids may be amenable to hysteroscopic resection, whereas submucosal, intramural, and broad-based subserosal fibroids are amenable to UFE. Cervical fibroids may not respond as well or have a durable response to embolization. Submucosal and intramural fibroids that contact the endometrium may be expelled following successful UFE in 2.2% to 7.7% of cases [1,25,66]. Pedunculated fibroids, depending on location and stalk caliber, may be treated hysteroscopically, laparoscopically, or with UFE [25]. Postcontrast imaging allows assessment of fibroid viability, uterine artery anatomy, and detection of ovarian arterial collateral supply to the uterus [67-71]. Nonviable/autoinfarcted fibroids, found in up to 20% of UFE candidates, do not respond to UFE and are therefore important to identify at time of treatment planning [71]. A meta-analysis on the utility of ADC values concluded that, because of heterogeneity, it is unclear whether ADC values are useful to predict UFE response [72].

Conventional MRI, however, cannot accurately differentiate fibroids from sarcomas, a critical distinction for surgical planning and optimizing outcomes [31-33]. Diffusion-weighted imaging with ADC, especially when

incorporated into an MRI algorithm, has shown promising results in distinguishing the two entities [20,34-40]. In a large, case-controlled retrospective study of women with atypical uterine masses, a diagnostic algorithm based on enlarged lymph nodes, peritoneal implants, high diffusion MRI signal, and low ADC values was developed and validated. The resulting algorithm achieved a 98% sensitivity and a 96% specificity in the training set and 83% to 88% sensitivity and 97% to 100% specificity in the validation sets [34]. Machine learning with texture analysis is under investigation and may have the potential to improve diagnostic accuracy [20].

For patients undergoing MRgFUS, prediction models and multivariate analyses have found that nonperfused volume, a surrogate of symptom improvement, is a function of fibroid signal intensity, peak and time to peak enhancement, subcutaneous fat thickness, and distance from spine. A nonperfused volume >80% predicted clinical success in more than 80% of patients [73-76].

US Pelvis Transabdominal
A combination of TAUS and TVUS of the pelvis is a frequently used imaging modality in pretreatment evaluation of known uterine fibroids [77,78]. TAUS is often useful in significantly enlarged fibroid uterus or large subserosal/pedunculated fibroids that may render poor visualization on TVUS because of limited field-of-view from poor acoustic penetration. A limitation of TAUS is a poor acoustic window from decompressed urinary bladder, retroverted uterus, large body habitus, and bowel gas [46].

US Pelvis Transvaginal
TVUS provides higher contrast and spatial resolution and should be combined with the TAUS whenever possible to evaluate suspected uterine fibroid [46,47]. TVUS has a reported sensitivity of 90% to 99% for detecting uterine fibroids and a sensitivity of 90% and specificity of 98% for the diagnosis of submucosal fibroids [43,48,49]. The limitations of TVUS are a limited depth of penetration and a shallow focal length that can limit the evaluation of large or subserosal/pedunculated fibroids. The presence of numerous fibroids may also pose challenge in clearly delineating and precisely measuring the fibroids because of too poor an acoustic window.

US Duplex Doppler Pelvis
Although Doppler imaging is labeled under separate imaging procedure per ACR methodology, this document considers it to be a standard component of pelvic US. Color and spectral Doppler are routinely used in pelvic US examinations to evaluate internal vascularity of pelvic/uterine findings and to differentiate between vascular and nonvascular tissue [47].

The growth of a uterine fibroid is proportional to its vascularity, and determining growth potential of the fibroid is helpful in clinical decision making [79,80]. Uterine artery Doppler flow measurements with peak systolic velocity >64 cm/s in uteri with fibroids have been shown as a predictor of UFE failure [81]. In a study by Nieuwenhuis et al [82], fibroid vascularization evaluated by 3-D TVUS with power Doppler correlated with fibroid volume and predicted fibroid growth rate per year. However, MRI pelvis has a higher sensitivity and accuracy than US in identifying number, location, size, volume, and vascularity of uterine fibroids for treatment planning [24,49,59].

Variant 3: Known fibroids. Surveillance or posttreatment imaging.

CT Pelvis
Although CT pelvis has no direct role in routine surveillance or posttreatment follow-up of uterine fibroids, CT, preferably with IV contrast, may be used following UFE in patients with pelvic pain, fever for acute postprocedural complications such as infection, hemorrhage, or pelvic venous thrombosis [83]. The overall serious post-UFE complication rate is 1.25%, with pulmonary embolism and infection (endometritis, pyometra, pyomyoma) occurring in up to 0.25% and 2% of patients, respectively [25,41,83].

MRI Pelvis
When MRI is clinically indicated, the use of a gadolinium-based IV contrast agent is preferred [26]. Please see the ACR Manual on Contrast Media for additional information [27].

Routine posttreatment surveillance is controversial, and there is no consensus when to image asymptomatic women postintervention. Most studies evaluate patients immediately, 3 months, and/or 12 months after treatment and rely on T1-weighted, T2-weighted, and postcontrast sequences. Parameters commonly assessed include uterine volume, fibroid volume, percent infarcted/nonperfused volume, ovarian arterial collateral supply to the uterus, and fibroid location [25,41,67,70,83-87]. Following technically successful UFE, >90% fibroid infarction on postcontrast imaging correlates with better symptom control and fewer reinterventions [88]. Fibroid location after treatment is also important, especially in cases of suspected fibroid expulsion, which occurs in 2.2% to 7.7% of cases [1,25,66].

Specifically, intracavitary devascularized fibroid location predisposes to fibroid expulsion. Several studies show an association between diffusion-weighted imaging and ADC values and fibroid devascularization after UFE and MRgFUS [89-94]. Quantitative perfusion parameters have also been used to predict immediate MRgFUS ablation response [95].

US Pelvis Transabdominal

A combination of TAUS and TVUS of the pelvis is a frequently used imaging modality in surveillance and posttreatment follow-up of known uterine fibroids [77,78]. TAUS is often useful in significantly enlarged fibroid uterus or large subserosal/pedunculated fibroids that can have poor visualization on TVUS because of limited field-of-view from poor acoustic penetration. Another potential limitation of TAUS is a poor acoustic window from decompressed urinary bladder, retroverted uterus, large body habitus, and bowel gas [46].

US Pelvis Transvaginal

TVUS provides higher contrast and spatial resolution and should be combined with TAUS whenever possible in surveillance or posttreatment follow-up of uterine fibroids [46,47]. Currently, there is no specific consensus on imaging surveillance of asymptomatic patients with fibroids [43,45,96]. TVUS remains an efficient modality in determining fibroid size-reduction post-UFE [78]. Following UFE, most of the fibroid size reduction occurs within the first 6 months, with a continued decrease in size between 6 and 12 months [77,97]. A treated fibroid may have varied sonographic appearance ranging from hypoechoic to heterogeneous increased echogenicity, primarily based on the histologic composition of the fibroids [77,78]. Gas may be seen within the treated fibroid secondary to infarction within 1 month following UFE [98]. Peripheral rim calcification has been described in UFE-treated fibroid ("fetal head sign") in contrast to the central dystrophic calcification from hyaline degeneration [77,99].

US Duplex Doppler Pelvis

Although labeled under separate imaging procedure per ACR methodology, this document considers Doppler imaging to be a standard component of pelvic US. Color Doppler has been routinely used in pelvic US examinations to evaluate internal vascularity of pelvic/uterine findings and differentiate between vascular and nonvascular tissue [47]. UFE results in a marked reduction in fibroid size and disappearance of intrafibroid vascularity without a reduction in uterine vascularization that can be assessed with Doppler US [100]. In a retrospective study of 227 patients treated with UFE for fibroids, Doppler evaluation showed a significant decrease in uterine artery peak systolic velocity (mean, 21.85 cm/s) relative to pre-embolization peak systolic velocity (mean, 40.33 cm/s) and correlated with a decrease in fibroid size and volume [81].

Summary of Recommendations

- **Variant 1**: US pelvis transabdominal, US pelvis transvaginal, and US duplex Doppler are usually appropriate for the initial imaging of clinically suspected fibroids. These procedures are complementary (ie, more than 1 procedure is ordered as a set or simultaneously in which each procedure provides unique clinical information to effectively manage the patient's care).

- **Variant 2**: US pelvis transabdominal, US pelvis transvaginal, US duplex Doppler, and MRI pelvis without and with IV contrast are usually appropriate for the initial imaging for treatment planning of known fibroids. These procedures are complementary (ie, more than one procedure is ordered as a set or simultaneously where each procedure provides unique clinical information to effectively manage the patient's care).

- **Variant 3**: US pelvis transabdominal, US pelvis transvaginal, US duplex Doppler, and MRI pelvis without and with IV contrast are usually appropriate for surveillance or posttreatment imaging of known fibroids. These procedures are complementary (ie, more than 1 procedure is ordered as a set or simultaneously in which each procedure provides unique clinical information to effectively manage the patient's care).

Supporting Documents

The evidence table, literature search, and appendix for this topic are available at https://acsearch.acr.org/list. The appendix includes the strength of evidence assessment and the final rating round tabulations for each recommendation.

For additional information on the Appropriateness Criteria methodology and other supporting documents go to www.acr.org/ac.

Appropriateness Category Names and Definitions

Appropriateness Category Name	Appropriateness Rating	Appropriateness Category Definition
Usually Appropriate	7, 8, or 9	The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients.
May Be Appropriate	4, 5, or 6	The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal.
May Be Appropriate (Disagreement)	5	The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned.
Usually Not Appropriate	1, 2, or 3	The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.

Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, because of both organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared with those specified for adults (see Table below). Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® Radiation Dose Assessment Introduction document [101].

Relative Radiation Level Designations		
Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	0 mSv	0 mSv
☢	<0.1 mSv	<0.03 mSv
☢☢	0.1-1 mSv	0.03-0.3 mSv
☢☢☢	1-10 mSv	0.3-3 mSv
☢☢☢☢	10-30 mSv	3-10 mSv
☢☢☢☢☢	30-100 mSv	10-30 mSv
*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (eg, region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."		

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