Abnormal Uterine Bleeding and Uterine Fibroids

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➲ Instructions for Use

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Related Commercial/Individual Exchange Policies
- Hysterectomy
- Preventive Care Services

Community Plan Policy
- Abnormal Uterine Bleeding and Uterine Fibroids

Medicare Advantage Policy
- Uterine Services and Procedures

Application

UnitedHealthcare Commercial
This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange
This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

➲ See Benefit Considerations

Endometrial Ablation
Endometrial ablation is proven and medically necessary for treating abnormal uterine bleeding in premenopausal individuals. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Hysteroscopy, Operative.

Click here to view the InterQual® criteria.

Levonorgestrel-Releasing Intrauterine Device
Levonorgestrel-releasing intrauterine devices (e.g., Mirena®, Skyla®, Liletta®, or Kyleena™) are proven and medically necessary for treating menorrhagia. Refer to the U.S. Food and Drug Administration (FDA) section for additional information.

Uterine Fibroids
Uterine artery embolization is proven and medically necessary for treating symptomatic uterine fibroids, postpartum or posthysterectomy bleeding, or uterine arteriovenous malformation. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Uterine Artery Embolization (UAE).

Click here to view the InterQual® criteria.

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Uterine artery embolization is unproven and not medically necessary for the purpose of preserving childbearing potential in individuals with symptomatic uterine fibroids due to insufficient evidence of efficacy.

Magnetic resonance–guided focused ultrasound ablation is unproven and not medically necessary for treating uterine fibroids due to insufficient evidence of efficacy.

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

CPT Code	Description
Uterine Fibroids	
0071T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue
0072T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
58563	Hysteroscopy, surgical; with endometrial ablation (e.g., endometrial resection, electrosurgical ablation, thermoablation)

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HCPCS Code	Description
Levonorgestrel-Releasing Intrauterine Device	
J7296	Levonorgestrel-releasing intrauterine contraceptive system, (Kyleena), 19.5 mg
J7297	Levonorgestrel-releasing intrauterine contraceptive system (Liletta), 52 mg
J7298	Levonorgestrel-releasing intrauterine contraceptive system (Mirena), 52 mg
J7301	Levonorgestrel-releasing intrauterine contraceptive system (Skyla), 13.5 mg
J7306	Levonorgestrel (contraceptive) implant system, including implants and supplies
S4981	Insertion of levonorgestrel-releasing intrauterine system

Description of Services

Abnormal uterine bleeding (AUB) in women of childbearing age is defined as any change in menstrual period frequency or duration, a change in amount of flow, or any bleeding between cycles. In postmenopausal women, AUB includes vaginal bleeding 12 months or more after the cessation of menstruation or unpredictable bleeding in those who have been receiving hormone therapy for 12 months or more. AUB terms include oligomenorrhea (bleeding occurs at intervals of more than 35 days), polymenorrhea (bleeding occurs at intervals of less than 21 days), menorrhagia (bleeding occurs at normal intervals but with heavy flow or duration of more than 7 days), menometrorrhagia (bleeding occurs at irregular, noncyclic intervals and with heavy flow or duration of more than 7 days), and metrorrhagia (irregular bleeding occurs between ovulatory cycles). Menorrhagia can be idiopathic or can be associated with underlying uterine lesions such as fibroids or polyps, pelvic pathology, anatomical abnormalities, systemic illness, hormonal imbalance, or certain medications. Idiopathic menorrhagia that is not related to a specific underlying condition is considered AUB. All these

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conditions that are associated with menorrhagia can be referred to as AUB, although it is also possible to have some conditions such as fibroids or an anatomical abnormality with normal menses. The focus in this policy is on treatment options when the bleeding pattern is abnormal.

Conservative management of AUB includes watchful waiting and pharmacological therapy. Hormone therapy may cause the fibroids to shrink; however, they will quickly return to their original mass once therapy has been discontinued. Another treatment option is dilation and curettage. Hysterectomy is available when symptoms cannot be controlled by conservative treatment.

According to the American College of Obstetricians and Gynecologists, fibroids are most commonly found in women who are aged 30 to 40 years but can occur at any age. Uterine fibroids (also known as leiomyomata) are benign tumors of the uterus. They have a rich blood supply and may cause excessive uterine bleeding, uterine enlargement and mass, or bulk related symptoms such as pelvic pain and pressure, urinary frequency, and abdominal distension. Uterine fibroid embolization (UFE) is indicated for individuals with clinically documented fibroids and fibroid-related symptoms and is a viable alternative to hysterectomy surgery. Recommendations prior to UFE treatment include an endometrial biopsy to rule out malignancy or hyperplasia (Bradley et al., 2019). Alternate minimally invasive procedures such as UFE are performed in an outpatient setting, resulting in shorter recovery times, less complications, and elimination of overnight hospital stays.

Levonorgestrel-Releasing Intrauterine Device

The local administration of the progestin levonorgestrel is delivered via an intrauterine device. The local delivery of this hormone causes the endometrium to become insensitive to ovarian estradiol, leading to atrophy of the endometrial glands, inactivation of the endometrial epithelium, and suppression of endometrial growth and activity.

Uterine Artery Embolization

This procedure injects particles via the uterine arteries to block blood supply to uterine fibroids, causing them to shrink.

Magnetic Resonance–Guided Focused Ultrasound

This procedure combines real-time magnetic resonance guidance with high-intensity focused ultrasound for the noninvasive thermal ablation of uterine fibroids. Tumor ablation is performed by focusing a collection of ultrasonic beams to increase sonic beam intensity at a point deep within the tissue to cause thermal coagulation while sparing normal tissues.

Benefit Considerations

Levonorgestrel-Releasing Intrauterine Device (LNG-IUD)

Certain intrauterine devices are included in the preventive care services benefit. Refer to the Medical Policy titled Preventive Care Services.

Some plan documents exclude coverage for contraception. In these plan documents, coverage for intrauterine devices (IUD), including the LNG-IUD, is excluded when used for contraceptive purposes. However, in these plan documents, coverage exists for the LNG-IUD when used for a non-contraceptive purpose, including treatment of abnormal uterine bleeding. Refer to the Coverage Rationale section above for medically necessary indications for coverage.

Clinical Evidence

Levonorgestrel-Releasing Intrauterine Device

Zhang et al. (2025) conducted a systematic review and meta-analysis that included 28 studies, of which nine were randomized controlled trials (RCTs) and 19 were non-RCTs, to summarize the evidence on the efficacy and safety of the levonorgestrel-releasing intrauterine system (LNG-IUS) in managing adenomyosis (AM), both as a monotherapy and in combination with other therapies. The primary outcome that was measured was dysmenorrhea, menstrual bleeding, uterine volume, endometrial thickness, and quality of life (QOL). The secondary outcome was the assessment of adverse events. The results of the review showed that compared with etonogestrel, LNG-IUS was more effective in reducing uterine volume and associated with a lower risk of weight gain but showed no significant difference in reducing dysmenorrhea and endometrial thickness. When LNG-IUS was compared with mifepristone, there was no significant difference in terms of QOL. The combination of LNG-IUS with gonadotropin-releasing hormone agonists (GnRH-as) was more effective than LNG-IUS alone, providing benefits in reducing dysmenorrhea, menstrual bleeding, uterine volume, endometrial thickness, and adverse events. The combination of LNG-IUS with surgical excision was more effective than

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surgical excision alone, providing benefits in reducing dysmenorrhea, menstrual bleeding at 12 months, and uterine volume at 6, 12, and 24 months. The combination of LNG-IUS with focused ultrasound ablation (FUA) was more effective than FUA alone, providing benefits in reducing dysmenorrhea and menstrual bleeding. The authors concluded that for single-drug therapy that is intended to improve pain and QOL, the current evidence does not support a conclusive recommendation for a favored treatment. For managing moderate to severe AM, LNG-IUS combined with GnRH-a is recommended, as this approach has demonstrated significant efficacy in reducing lesion volume, alleviating pain, controlling heavy menstrual bleeding, inducing endometrial atrophy, reducing the probability of expulsion, and mitigating irregular bleeding. Concerning surgical interventions, the addition of postoperative LNG-IUS offers benefits in reducing long-term pain and menstrual bleeding; the authors speculated that younger individuals or those who are experiencing significant pain and bleeding might benefit from this combined therapy with LNG-IUS. Moreover, in the context of combined FUA, LNG-IUS has shown advantages in managing short-term pain and menstrual bleeding, but the long-term superiority remains unclear. It is advised that those who are presenting with severe symptoms receive LNG-IUS as soon as possible following the intervention. However, more high-quality research is needed to further evaluate the effect and safety in more than 12 months.

In a clinical trial of the MIRA trial, which was a multicenter RCT, Huijs et al. (2024) sought to assess the long-term differences in the reintervention risk and menstrual blood loss in women with the symptoms of heavy menstrual bleeding (HMB) treated according to a strategy starting with a 52-mg LNG-IUS or radiofrequency nonresectoscopic endometrial ablation. The participants of the trial were separated into two groups: those receiving a 52-mg levonorgestrel-releasing intrauterine device (LNG-IUD; n = 132) or radiofrequency on resectoscopic endometrial ablation (n = 138). The outcomes that were measured were the reintervention rate, menstrual bleeding, QOL, sexual function, and participant satisfaction. The results of the trial showed that from the 270 women who were randomized in the original trial, 196 (52-mg LNG-IUS group: n = 94; radiofrequency nonresectoscopic endometrial ablation group: n = 102) took part in this long-term follow-up study. The cumulative reintervention rate (including both medical and surgical reinterventions) was 40.0% (34 of 85) in the 52-mg LNG-IUS group and 28.7% (27 of 94) in the radiofrequency nonresectoscopic endometrial ablation group (relative risk, 1.39; 95% CI, 0.92-2.10). The cumulative rate of surgical reinterventions was only significantly higher in those with a treatment strategy starting with a 52-mg LNG-IUS compared with radiofrequency nonresectoscopic endometrial ablation [35.3% (30 of 85) vs 19.1% (18 of 94); relative risk, 1.84; 95% CI, 1.11-3.10]. However, the hysterectomy rate was similar [11.8% (10 of 94) in the 52-mg LNG-IUS group and 18.1% (17 of 102) in the radiofrequency nonresectoscopic endometrial ablation group; relative risk, 0.65; 95% CI, 0.32-1.34]. Most reinterventions occurred during the first 24 months of follow-up. A total of 171 Pictorial Blood Loss Assessment Chart scores showed a median bleeding score of 0.0. No clinically relevant differences were found regarding QOL, sexual function, and participant satisfaction. The limitation of the study is the possibility that the responders to the long-term follow-up may only represent part of the original study population. Additionally, the cause of the symptom of HMB was not assessed at baseline following the International Federation of Gynecology and Obstetrics classification. Lastly, a natural consequence of the long-term follow-up is that participants became postmenopausal during this period, given that the average age at baseline was approximately 45 years. The high proportion of postmenopausal women is another limitation of the current study, given that postmenopausal status could be conflated with optimal treatment effect. The authors concluded that the overall risk of reintervention after long-term follow-up was not different between women who were treated according to a treatment strategy starting with a 52-mg LNG-IUS and those treated using a strategy starting with radiofrequency nonresectoscopic endometrial ablation. However, women who were given a treatment strategy starting with a 52-mg LNG-IUS had a higher risk of surgical reintervention, which was driven by an increase in later endometrial ablation. Both treatment strategies effectively lowered menstrual blood loss over the long term. The results of this long-term follow-up study can support physicians in improving the counseling of women with HMB, thus promoting informed decision-making regarding the choice of treatment (ClinicalTrials.gov ID: NCT07581288).

In a 2024 systematic review and single-arm meta-analysis, Oliveira et al. examined the LNG-IUS in women with inherited bleeding disorders and HMB. The exploration uncovered six observational studies (n = 156) that met the inclusion criteria. The results of the review showed that LNG-IUS use in those with inherited bleeding disorders and HMB was associated with amenorrhea in 60% of people and a significant increase of 1.40 g/dL in hemoglobin and 19.75 ng/mL in ferritin levels when comparing post- and pretreatment levels. The posttreatment mean hemoglobin was 13.32 g/dL, and the mean ferritin was 43.22 ng/dL. The rate of intrauterine device expulsion or removal due to malposition was low (13%), as was the need for IUD removal due to lack of efficacy (14%). The limitations include the need for more of a control group, small number of studies, and lack of individual patient-level data, which precludes a more robust analysis of personal factors that may be associated with better or worse efficacy of the LNG-IUS in this group. The authors concluded that the LNG-IUS may improve bleeding patterns and QOL in those with inherited bleeding disorders and HMB.

Lee et al. (2024) conducted a systematic review and meta-analysis to investigate the effectiveness of high-intensity focused ultrasound (HIFU) combined with GnRH-a or LNG-IUS in people with AM. The outcomes that were measured were the treatment efficacy rate of dysmenorrhea, effective rate of menorrhagia severity, and reduction rate of AM lesion.

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Adverse events were also assessed. The results uncovered that HIFU plus LNG-IUS showed lower dysmenorrhea [within 6 months: risk ratio (RR), 0.88, 95% CI, 0.83-0.93, p < 0.00001; over 1 year: RR, 0.73, 95% CI, 0.65-0.82, p < 0.00001] and less menorrhagia severity (RR, 0.63; 95% CI, 0.60-0.66; p < 0.00001) than HIFU plus GnRH-a. Both groups had equal efficacy in adenomyotic lesion reduction rate (RR, 1.03; 95% CI, 0.97-1.09; p = 0.30). Adverse effects happened equally in both groups. The limitations of the study include the significant heterogeneity, retrospective nature of research, lack of randomization, allocation, and blinding process. The authors concluded that combination therapy of HIFU and LNG-IUS showed better results in the effectiveness of treating dysmenorrhea and menorrhagia compared with HIFU and GnRH-a.

Chen et al. (2022) compared the safety and efficacy of the LNG-IUS with those of other medical treatments for women with HMB. A search was conducted using the CENTRAL (Cochrane Central Register of Controlled Trials), PubMed, Embase, and Wanfang databases. Overall, 13 RCTs were retrieved for the systematic review, and 12 were included for meta-analyses. In total, 1,677 individuals were included, with the average age ranging from 28 to almost 42 years of age; all were diagnosed with HMB. Included RCTs compared LNG-IUS against medical treatments. The LNG-IUS used was a continuous release system of intrauterine progesterone and comprised 52 mg of levonorgestrel, which was released at a rate of approximately 20 µg/day during the first year. The medical treatments included oral hormonal drugs and tranexamic acid. The primary outcome that was assessed was clinical response to treatment, and the secondary outcomes included menstrual blood loss, QOL, adverse events, and individuals' satisfaction. The Cochrane risk-of-bias tool was used for assessment of the risk of bias in the included RCTs. The authors found that the number of clinical responders was greater in the LNG-IUS group than the medical treatment groups. It was concluded that the evidence was superior for LNG-IUS in the short- and medium-term clinical responses, blood loss control, adherence, and satisfaction compared with that for medical treatments. Limitations include the lack of long-term data, high risk of performance bias due to the blinding of individuals and personnel, and self-reported data.

Evidence from a Cochrane systematic database review by Bofill Rodriguez et al. (2022) suggests that LNG-IUS is the best first-line action for reducing menstrual blood loss. The authors synthesized the results of studies that focused on different treatments for HMB. Treatments were categorized based on individuals' characteristics, including the desire for future pregnancy, failure of previous treatment, or referral for surgery. The data analyzed included 9,950 individuals from 85 studies. The medical treatments included nonsteroidal anti-inflammatory drugs (NSAIDs), antifibrinolytics, combined oral contraceptives, combined vaginal ring, long-cycle and luteal oral progestogens, the LNG-IUS, ethamsylate, and danazol and were compared with a sham treatment. Surgical interventions included open, minimally invasive, and unspecified routes for hysterectomy, resectoscopic endometrial ablation, nonresectoscopic endometrial ablation, and unspecified endometrial ablation. In nonsurgical candidates, LNG-IUS was the most effective first-line treatment to reduce menstrual blood loss. For surgical candidates, hysterectomy was the most effective treatment for reducing menstrual blood loss and to avoid further surgery for HMB. Future research should assess the efficacy and safety of progestogen-only contraceptives and compare them with those of different combined hormonal contraceptives for the treatment of HMB, in addition to assessment of QOL.

A 2020 Cochrane systematic database review by Bofill et al. found that the LNG-IUS had a greater reduction in menstrual blood loss in women with HMB compared with other medical treatments or placebos; the authors' conclusion was that LNG-IUS appears to be more effective than oral medical therapies and results in better QOL and higher satisfaction. The analysis included 25 RCTs, which included a total of 2,511 women; most studies did not provide long-term data beyond 2 years. Limitations include the small number of individuals in the differing trials and a high-risk of bias for blinding.

Cim et al. (2018) reported 2-year follow-up data from people with abnormal uterine bleeding (AUB) after insertion of the LNG-IUS. Overall, 106 parous women who were aged 33 to 48 years and had recurrent HMB participated in this study and were followed up for 1, 3, 6, 12, 18, and 24 months following the insertion. The authors reported that all women well tolerated the LNG-IUS. Prior to treatment with the use of the LNG-IUS, endometrial biopsy patterns for irregular proliferative endometrium and for atypical simple hyperplasia were 34 of 106 (32.08%) and 61 of 106 (57.55%), respectively, and after treatment no abnormal pathological findings were determined (p < 0.001).

Louie et al. (2017) evaluated comparative clinical outcomes after placement of LNG-IUS, ablation, or hysterectomy for AUB. A decision tree was generated to compare clinical outcomes in a hypothetical cohort of 100,000 premenopausal women with nonmalignant AUB. Complications, mortality, and treatment outcomes were evaluated over a 5-year period, with calculated cumulative quality-adjusted life-years and probabilistic sensitivity analysis. The LNG-IUS had the highest number of quality-adjusted life-years (406, 920), followed by hysterectomy (403, 466), nonresectoscopic ablation (399, 244), and resectoscopic ablation (395, 827). Ablation had more treatment failures and complications than LNG-IUS and hysterectomy. According to the authors, the findings were robust in sensitivity analysis.

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Uterine Artery Embolization

There is insufficient evidence to conclude that the treatment of fibroids with uterine artery embolization (UAE) preserves childbearing potential. Most studies on UAE's impact on fertility are low quality and have a small sample size, which limits the generalizability of the findings. There is also a scarcity of long-term follow-up data on fertility and pregnancy outcomes after UAE, with some studies suggesting a higher risk of pregnancy complications. Additional research that involves larger, robust RCTs is needed to establish safety, effectiveness, and long-term outcomes.

Bucuri et al. (2025) conducted a systematic review and random-effects meta-analysis (RevMan 5.4) of fertility outcomes after uterine artery embolization (UAE) in women with symptomatic uterine fibroids, including peer-reviewed studies with histopathology data that reported fertility outcomes at least 6 months after UAE with a clear denominator and excluding small case reports (< 5 patients), duplicate publications, unclear denominators, mixed indications without separate reporting, and follow-up shorter than 6 months. Across 33 studies including 4,287 women, fertility outcomes were assessed in 3,654 patients (85.2% follow-up), with primary outcomes defined as pregnancy rates (among women trying to conceive after UAE, excluding those using contraception or not sexually active, or when intention was not specified, women of child-bearing age with documented follow-up) and time to conception (months from the UAE date/procedure date); pooled pregnancy outcomes from 29 studies showed a pregnancy rate of 52.1% (95% CI 46.8-57.4%), and pooled mean time to conceive after UAE was 14.7 months (95% CI 11.2-18.2) based on 18 studies. The authors concluded that UAE can preserve fertility in approximately 50% of selected patients with better outcomes in younger women, and that UAE is an option to ordinary surgery for women seeking a minimally invasive intervention but there is no evidence to confirm it is similar to myomectomy as the gold standard conservative treatment. There are limitations, including major drawbacks in the comparative evidence such as selection bias, inconsistent surgical experience, and uneven follow-up time of 24-48 months. Because most studies were observational and not randomized, causal inference was restricted and confounding by indication was likely, as UAE and myomectomy patients differed in baseline characteristics and measured confounders did not fully explain systematic differences. Follow-up ranged from 12 to > 60 months and could not easily be pooled, which might have underestimated long-term fertility, and inconsistent definitions of pregnancy and time-to-event outcomes further reduced comparability. Negative findings, particularly adverse events such as ovarian dysfunction, PTS, or the need for a second hysterectomy, may be underrepresented, and selective reporting distorted complication estimates despite low funnel-plot and Egger-test asymmetry for pregnancy results. UAE does not provide tissue for microscopic examination, so there is no linkage to histopathological confirmation, limiting demonstration of benign lesions, identification of uncommon malignancies such as leiomyosarcoma, and assessment of degenerative fibroid changes beyond imaging.

Peng et al. (2024) conducted a systematic review and meta-analysis of current evidence comparing the efficacy of UAE vs. that of myomectomy (MYO) for managing symptomatic uterine fibroids (UFs) in women who were opposed to undergoing a hysterectomy. A meta-analysis was completed for all available studies that assessed the relative benefits and harms of MYO and UAE for managing individuals with UFs. The outcomes that were evaluated were reintervention, UFs scores for QOL, and symptom severity, along with other complications. The results of the meta-analysis show that UAE had a higher reintervention rate, hysterectomy rate, and symptom severity score than MYO at a 4-year follow-up. However, UAE was associated with a lower rate of early complications and readmission rate compared with MYO. Additionally, both procedures had similar improvement in pregnancy rates and AUB. The limitations of the study include the outcomes being tied to time, so variation in follow-up length might affect late-occurring events. Next, most of these studies were observational. More matched studies are required for specific groups of individuals. Lastly, the outcomes were inconsistent among papers, limiting the quantity of articles to synthesize, which potentially introduces selection bias. The authors concluded that UAE and MYO are effective in treating symptomatic UFs but that they have different outcomes. The decision on which procedure to choose should be made based on individual preferences and the physician's expertise.

In 2023, Yan et al. conducted a systematic review with trial sequential analysis that aimed to focus on pregnancy rate and outcomes in female individuals after UAE. A subgroup analysis was also performed based on different populations of individuals or various control treatments. The overall results revealed that UAE significantly decreased the postoperative pregnancy rate (relative risk, 0.721; 95% CI, 0.531-0.979; 95% prediction interval, 0.248-2.0970) and was associated with an increased risk of postoperative postpartum hemorrhage (PPH; relative risk, 3.182; 95% CI, 1.319-7.675; 95% prediction interval, 0.474-22.089). An analysis grouped by population indicated that UAE decreased the risk of preterm delivery (relative risk, 0.326; 95% CI, 0.128-0.831; p = 0.019) and cesarean section (relative risk, 0.693; 95% CI, 0.481-0.999; p = 0.050) and increased the risk of placenta previa (relative risk, 8.739; 95% CI, 1.580-48.341; p = 0.0130) in those with UFs, cesarean scar pregnancy, and PPH, respectively. Compared with MYO, HIFU, and nonuse of UAE, UAE treatment was associated with the reduced risks of preterm delivery (relative risk, 0.296; 95% CI, 0.106-0.826) and cesarean section (relative risk, 0.693; 95% CI, 0.481-0.999; p = 0.050) and increased placenta previa risk (relative risk,10.682; 95% CI, 6.859-16.636), respectively. Limitations of the study include the heterogeneity, lack of specificity whether the individuals in the research suggested exclusively from a single disease, and insufficient number of studies to

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continue subanalysis by subgroup 1 and subgroup 2. The authors concluded that UAE treatment was associated with a lower postoperative pregnancy rate and increased risk of PPH. The subgroup analysis suggests that UAE was shown to decrease the risk of preterm delivery and cesarean section and increase placenta previa risk.

Akhatova et al. (2023) conducted a systematic review that compared and assessed UAE, ultrasound-guided HIFU (US-HIFU), magnetic resonance–guided HIFU (MR-HIFU), and transcervical radiofrequency ablation (TFA) procedures. A search using PubMed, Google Scholar, ScienceDirect, Cochrane Library, Scopus, Web of Science, and Embase was performed and returned 25 articles. The number of pregnancies varied considerably among the studies as well as the mean age of the women; the studies usually included women who were > 40 years of age. The rates of live births for UAE, HIFU, and TFA were similar at 70.8%, 73.5%, and 70%, respectively. The miscarriage rate was the greatest in the UAE group, which accounted for 19.2%. Overall, the delivery rate by cesarean section was greater with these minimally invasive procedures compared with that for the general population rate (31.8%); this was most likely due to the greater risks associated with women with UFs. On analysis, the authors found that the estimation of pregnancy was found to be higher after UAE and HIFU compared with TFA. The evidence confirmed that minimally invasive uterine-sparing treatment options for UFs, such as UAE, HIFU, and TFA, are a good approach for those wishing to preserve their fertility. Future studies should include additional robust studies to help identify which subpopulation would benefit most from receiving one technique vs another. Limitations include the retrospective design, low total number of pregnancies after TFA available for analysis, and lack of data around the size, location, and number of fibroids, which are known to influence treatment.

Mailli et al. (2023) conducted a literature review on UAE treatment for symptomatic fibroids, which included a focus on postprocedure fertility outcomes. A search of the literature was performed using the PubMed/MEDLINE, Google Scholar, Cochrane, and Embase databases. The search resulted in 18 articles for review: two RCTs, two prospective controlled studies, seven prospective cohorts, four retrospective cohorts, and three case series. One key factor that was identified during the research was the age of the individuals and the effect on fertility; studies that included women who were over the age of 40 had a negative impact on fertility. However, the overall mean age was 35.9 years, thus the authors suggested that UAE could be considered in younger people who have a desire to preserve fertility. The authors concluded that the evidence does support UAE as a viable treatment option in women with large fibroids and who are seeking to preserve fertility; however, future RCTs are warranted.

Karlsen et al. (2018) conducted a systematic review of the reported rates of pregnancy and miscarriage after treatment of UFs with UAE. RCTs, controlled clinical trials, comparative before-after trials, cohort studies, case-control studies, and case series in which UAE treatment in premenopausal women was performed for UFs, with and where a control intervention was included. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guideline was used to do a systematic review using the main outcomes of pregnancy rate and miscarriage rate. Risk of bias was assessed by the Cochrane risk-of-bias tool or by ROBINS-I (Risk of Bias in Non-Randomized Studies of Interventions). The quality of evidence was assessed by the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach. Overall, 17 studies, comprising 989 individuals, were selected and included one RCT, two cohort studies, and 14 case series. The results showed that pregnancy rates after UAE were 50% in the RCT and 51% and 69% in the cohort studies. Among the case series, the median pregnancy rate was 29%. The miscarriage rate was 64% in the RCT. Miscarriage rates at 56% and 34% were found in the cohort studies after UAE. The median miscarriage rate was 25% in the case series. The authors concluded that the pregnancy rate was found to be lower and miscarriage rate higher after UAE than after MYO. However, they found very low quality of evidence regarding the assessed outcomes, and the reported proportions are uncertain. There is a need for improved prospective randomized studies to improve the evidence base.

The Agency for Healthcare Research and Quality published a comparative effectiveness review on the management of UFs that was designed to review the treatment effectiveness and the risk of leiomyosarcoma in women with fibroids. The review found high strength evidence that UAE is effective for reducing the size of fibroids and total fibroid volume. Improvements in bleeding and QOL had a moderate strength of supporting evidence. Over half of the women who received UAE did not require a subsequent intervention after a 5-year follow-up period. Insufficient evidence was found to determine the safety of the UAE on reproductive outcomes. Additionally, the uncertainty in estimates of leiomyosarcoma prevalence and evolving data about methods for tissue extraction require exploration (Hartmann et al., 2017).

Magnetic Resonance–Guided Focused Ultrasound Ablation

There is insufficient evidence to conclude that magnetic resonance–guided focused ultrasound (MRgFUS) ablation is effective in treating fibroids. There is a paucity of long-term studies on the durability of symptom relief and fibroid recurrence after MRgFUS treatment. There is a lack of standardization of treatment protocols, which can lead to variability in outcomes. Additional research that involves larger, robust RCTs is needed to establish its safety, efficacy, and long-term outcomes.

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Otonkoski et al. (2025) reported a prospective, single-center follow-up study of MR-guided high-intensity focused ultrasound (MR-HIFU) in 175 women with at least one symptomatic uterine fibroid who were deemed suitable for MR-HIFU treatment, assessing fibroid-related symptoms and quality of life using the uterine fibroid-specific quality of life questionnaire (UFS-QoL) with symptom severity score (SSS) and QoL measured at baseline and at 3 and 12 months. Using paired Wilcoxon signed-rank tests and analyses that included all available questionnaires even if a patient did not have responses for all timepoints, the primary outcome (fibroid-related symptoms) improved with median SSS decreasing from 56 (IQR 44–69) at baseline to 28 (IQR 16–44) at 3 months ($p < 0.01$) and 25 (IQR 16-38) at 12 months ($p < 0.01$); the pre-specified secondary outcome was reintervention rate. The authors concluded that MR-HIFU significantly reduces the severity of fibroid-related symptoms in selected patients as early as 3 months after treatment and that the effect persists at 12 months. There are limitations, including that no record of rejected patients was kept, so the exact proportion is not known. Key limitations included a relatively short follow-up time of 12 months; notwithstanding this, the reintervention rate for fibroid-related symptoms was extremely low at 2%. This limits interpretation because the results may not necessarily correlate with the efficacy of MR-HIFU treatment in a general fibroid population.

In a 2024 systematic review and meta-analysis, Dou et al. sought to quantify the reintervention rate and analyze the risk factors for reintervention after HIFU ablation of UFs. The study enrolled 5,216 individuals with fibroids that were treated with HIFU. There were 3,247, 1,239, 1,762, and 2,535 reaching reintervention rates of 1% (95% CI, 1%-1%), 7% (95% CI, 4%-11%), 19% (95% CI, 11%-27%), and 29% (95% CI, 14%-44%) at 12, 24, 36, and 60 months after HIFU. The reintervention rates in those who were treated with US-HIFU were significantly lower than the rates in those who were treated with MRgFUS. When the nonperfused volume rate (NPVR) of fibroids was over 50%, the reintervention rates at 12, 36, and 60 months after HIFU were 1% (95% CI, 0.3%-2%), 5% (95% CI, 3%-8%), and 15% (95% CI, 9%-20%). The reintervention risk for hypo-/isointensity fibroids on T2-weighted imaging was 3.45 times higher (95% CI, 2.7-4.39) for hypo-/isointensity fibroids. The limitations of the study include the inclusion of several observation studies due to the limited availability of literature on the long-term outcomes of this treatment. The authors concluded that the overall reintervention rates after HIFU were acceptable and provided consultative suggestions regarding treatment alternatives for those with fibroids. The subgroup analysis revealed that US-HIFU, NPVR of ≥ 50%, and isointensity of fibroids on T2-weighted imaging were significant factors in reducing intervention.

Through a systematic review and meta-analysis, Hu et al. (2023) compared HIFU and laparoscopic treatment of UFs. Overall, 1,375 articles were received in the literature, 14 of which were selected. The authors found that women who underwent HIFU surgery had higher rates of spontaneous pregnancy, higher rates of spontaneous delivery, and higher rates of full-term delivery but may have had higher rates of miscarriage or postpartum complications than women who underwent laparoscopic MYO. Limitations of the study include insufficient controlled studies; therefore, single-group rates were counted in this study, subgroup analysis was used, and no comparisons were made between the two groups. No ratio data could be generated, leading to an absolute inability to discuss the sources of heterogeneity using regression analysis. The authors concluded that HIFU is not worse than laparoscopic MYO in terms of fertility and is even better regarding spontaneous pregnancy rates, spontaneous labor, and full-term delivery. HIFU is a better choice for women with fibroids and fertility requirements.

Kociuba et al. (2023) evaluated the most common adverse events and complications in people following MRgFUS therapy for UFs. A literature search using PubMed/MEDLINE, Scopus, and CENTRAL returned 43 publications for analysis, which totaled 3,102 individuals; most studies were cohorts with only two RCTs. Overall, the risk-of-bias assessment categorized 23 studies as low, eight studies as moderate, and 12 studies as being at a high risk of bias based on the reported adverse events. Three types of devices were identified for use in treating the UFs (ExAblate 2000/2100, Sonalleve V1/V2, and Chongqing Haifu JM 2.5 C/JM 5100), with the ExAblate 2000 device being the most popular (in 22 studies), which had a mean occurrence of 18.03% for adverse events. Sonalleve was the second most popular device found in 11 studies, with a mean occurrence of 40.3% for adverse events. Pain (pelvic/abdominal) was the most common reported adverse event, along with first- or second-degree skin burns, rashes, or ulcerations being the next. The authors concluded that MRgFUS is a relatively safe choice in UF therapy, with the occurrence of adverse events being rather low, in addition to very few major adverse events identified. However, the authors did find nerve damage as another clinical problem that should be considered as a potentially serious adverse event in an individual when performing MRgFUS. Limitations include the small sample size with short follow-up time; lack of pain assessment tools; and unclear definition of an adverse event. Future prospective RCTs in larger populations and long-term outcomes are necessary to determine the safety and efficacy of the procedure.

An ECRI (2022) Clinical Evidence Assessment for HIFU indicates that the evidence may be somewhat favorable based on a review of five systematic reviews with meta-analysis. An evidence assessment included results for symptom relief, QOL, reintervention rate, hospital stay, recovery time, postprocedure pregnancy rate, and adverse events. Compared with surgery, HIFU was associated with fewer adverse events, shorter hospital stays, and better QOL after 1 year. Compared

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with UAE, HIFU demonstrated less improvement in QOL, less symptom relief, and a higher reintervention rate. Future high-quality RCTs that assess long-term outcomes are warranted, in addition to standardized HIFU protocols.

A Hayes report (2019; updated 2022) concluded that although evidence suggests that MRgFUS reduces fibroid volume in women with symptomatic fibroids, the overall quality of the evidence is low due to the lack of well-designed, controlled studies. Substantial uncertainty remains regarding the effect of magnetic resonance–guided FUA of UFs on symptoms and the comparative effectiveness with other treatment alternatives.

Yu et al. (2021) conducted a comparative meta-analysis on the efficacy and safety of MR-HIFU and US-HIFU. Overall, 48 studies were included for review; 28 addressed the MR-HIFU, and 20 focused on US-HIFU. UFs with a volume of < 300 cm^3 were part of the inclusion criteria. NPVR is considered a significant parameter that is positively connected with clinical success rate. An NPVR for the MR-HIFU was 58.92%, which was lower than that in the US-HIFU group, which was 81.07%. An NPVR of greater than 80% was considered successful. The average treatment time for MR-HIFU was almost double that of US-HIFU, which had a mean of 96.9 minutes. For the treatment of symptomatic UFs, the authors' conclusions revealed that the ultrasound procedure had greater safety and efficacy than the magnetic resonance procedure. Limitations include a loss of follow-up in the majority of the studies, poor documentation for number and location of fibroids, and lack of long-term outcomes.

In a 2019 systematic review (included in the 2019 Hayes report), Taheri et al. examined the change in uterine and fibroid volumes associated with UAE, focused ultrasound, and radiofrequency ablation (RFA). Overall, 81 relevant papers were identified: 52 related to UAE, 11 related to RFA, 17 related to focused ultrasound, and one that compared UAE and focused ultrasound. Uterine volume and fibroid volume changes seen in these studies were at 1 to 36 months. The pooled fibroid volume reduction at 6 months seen with RFA was 70%, with UAE was 54%, and with focused ultrasound was 32%. All three types of nonrespective treatment resulted in fibroid volume reduction. However, fibroid volume reduction was most marked with RFA, with UAE resulting in the next most volume reduction. Additional larger cohort studies, including those that are randomized and/or comparative, would enable definitive conclusions.

Ierardi et al. (2018) performed a systematic review for percutaneous ablation on UFs. The primary end point was to investigate the feasibility and safety of the technique. Six articles that contained 541 individuals were evaluated, and no major complications with the procedure were found. After reviewing the data, the authors concluded that microwave ablation of UFs was safe and effective; however, larger, randomized, prospective trials are needed to better demonstrate the benefits. The authors found that a major limitation of MRgFUS is that many women are not eligible for the procedure due to potential challenges and risks associated with visceral injury.

Barnard et al. (2017; included in the 2022 ECRI and the 2019 Hayes reports and the Kociuba et al., 2023, systematic review above) conducted an RCT and comprehensive cohort analysis to compare the periprocedural outcomes of fibroid embolization and those of focused ultrasound. Premenopausal women with symptomatic UFs who were seen at three U.S. academic medical centers were enrolled in the RCT (n = 57). Women who met identical criteria and declined randomization but agreed to study participation were enrolled in a nonrandomized parallel cohort (n = 34). The two treatment groups were analyzed by using a comprehensive cohort design. All women who were undergoing focused ultrasound and UAE received the same postprocedure prescriptions, instructions, and symptom diaries for comparison of recovery in the first 6 weeks. Return to work and normal activities, medication use, symptoms, and adverse events were captured with postprocedure diaries. Data were analyzed using the Wilcoxon rank sum test or $\chi 2$ test. Multivariable regression was used to adjust for baseline pain levels and fibroid load when comparing opioid medication, adverse events, and recovery time between treatment groups because these factors varied at baseline between groups and could affect outcomes. Adverse events were also collected. The results showed that focused ultrasound surgery was a longer procedure than embolization, with 23 (over half) women undergoing focused ultrasound for 2 treatment days. Immediate self-rated postprocedure pain was higher after UAE than focused ultrasound. Compared with those who had focused ultrasound (n = 39), women who were undergoing embolization (n = 36) were more likely to use outpatient opioid (75% vs 21%) and NSAIDs (97% vs 67%) and to have a longer median recovery time (days off work, 8 vs 4; days until return to normal, 15 vs 10). There were no significant differences in the incidence or severity of adverse events between treatment arms; 86% of adverse events (42 of 49) required only observation or nominal treatment, and no events caused permanent sequelae or death. After adjustment for baseline pain and UF load, UAE was still significantly associated with higher opioid use and longer time to return to work and normal activities. Results were similar when restricted to the RCT. The authors discussed the challenges that have inhibited mainstream adoption of MRgFUS, and they include the prolonged duration of most procedures; participant eligibility, with numerous exclusion criteria; and restrictive selection criteria. The authors concluded that more comparative trials are needed to assess MRgFUS against other more established uterine-preserving treatments.

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In a clinical assessment, ECRI concluded that the evidence for the ExAblate Body System was inconclusive. The evidence suggests that the ExAblate reduces symptoms and improves QOL in women for up to 3 years; however, the studies have a high risk of bias and report on too few outcomes to be conclusive on how well it works. The evidence was limited by a small sample size, retrospective design, high attrition of individuals, and lack of control groups, randomization, and blinding (ECRI, 2017; updated 2020).

Clinical Practice Guidelines

American Association of Gynecologic Laparoscopists (AAGL)

In a position statement on the treatment of submucous leiomyomas, the AAGL (2012) states that with currently available evidence, embolic and ablative therapies are not appropriate for women with submucous myomas who have current infertility or who wish to conceive in the future. These techniques include UAE and occlusion as well as leiomyoma ablation with radiofrequency electricity, cryotherapy, and MRgFUS [based primarily on consensus and expert opinion (level C)]. The AAGL recommends long-term studies on the impact of various ablation techniques on the symptom of HMB in women with submucous leiomyomas.

American College of Obstetricians and Gynecologists (ACOG)

An ACOG committee opinion on uterine morcellation for presumed leiomyomas recommends that women should be evaluated to determine increased risk of malignancy of the uterine corpus before considering morcellation of the uterus. The preoperative evaluation should include risk stratification and use of imaging, cervical cancer screening, and endometrial tissue sampling to identify malignancy. Additionally, the patient should be informed of the possible risk of disseminating occult uterine malignancy by open morcellation as well as the risk of disseminating benign uterine tissue. Shared decision-making between the obstetrician-gynecologist and patient should include informed consent, explanation of risk and benefits of each approach to surgery for presumed leiomyomas, alternatives to morcellation, and the risk and benefits of morcellation (ACOG, 2021).

An ACOG committee opinion on acute AUB concludes that surgical management should be considered for those who are not clinically stable, are not suitable for medical management, or have not responded appropriately to medical management. The choice of surgical management should be based on the patient's underlying medical conditions, underlying pathology, and desire for future fertility (ACOG, 2013; reaffirmed 2020).

Levonorgestrel-Releasing Intrauterine Device

In a practice bulletin on the management of symptomatic uterine leiomyomas, ACOG states that the LNG-IUD may be considered for treatment of AUB; however, there is insufficient evidence to support their use for the treatment of any other uterine leiomyoma symptoms other than bleeding (ACOG, 2021).

An ACOG practice bulletin on the use of noncontraceptive uses of hormonal contraceptives says the following:

- Combined oral contraceptives have been shown to regulate and reduce menstrual bleeding, treat dysmenorrhea, reduce premenstrual dysphoric disorder symptoms, and ameliorate acne (evidence level A; based on good and consistent scientific evidence).
- Hormonal contraception should be considered for the treatment of menorrhagia in women who may desire further pregnancies (evidence level B; based on limited or inconsistent scientific evidence).

(ACOG, 2010; reaffirmed 2020)

Magnetic Resonance Imaging–Guided Focused Ultrasound Ablation

In a practice bulletin on the management of symptomatic uterine leiomyomas, ACOG states that while limited, low-quality data suggest that MRgFUS is associated with a reduction in leiomyoma and uterine size, smaller randomized, comparative data suggest that when compared with UAE, MRgFUS is associated with less improvement in symptoms and a higher rate of reintervention (ACOG, 2008; reaffirmed 2021).

Uterine Artery Embolization

In a practice bulletin for AUB, ACOG states that an office endometrial biopsy is the first-line procedure for tissue sampling in the evaluation of people with AUB. Endometrial sampling should be performed in individuals who are younger than 45 years of age for persistent AUB and failed medical management (ACOG, 2012; reaffirmed 2016).

In a practice bulletin on the management of symptomatic uterine leiomyomas, ACOG states that UAE is recommended as a procedure for the treatment of uterine leiomyomas in women who desire uterine preservation and that these women should be counseled on the limited available data for reproductive outcomes (ACOG, 2008; reaffirmed 2021).

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American College of Radiology (ACR)

The ACR revised its appropriateness criteria for managing UFs in 2023. A summary of recommendations is as follows:

- Laparoscopic or open MYO, medical management, MRgFUS, or UAE is usually appropriate for the initial therapy in a patient who is of reproductive age, has UFs, is symptomatic with heavy uterine bleeding or bulk symptoms (e.g., pressure, pain, fullness, bladder, or bowel symptoms), and has a desire to preserve fertility. In most cases, medical management should be trialed before pursuing more invasive therapies. The procedures are equivalent alternatives (i.e., only one procedure will be ordered to provide the clinical information to manage the patient's care effectively).
- Laparoscopic or open MYO, medical management, MRgFUS, or UAE is usually appropriate for the initial therapy in a patient who is of reproductive age, has UFs, is symptomatic with heavy uterine bleeding or bulk symptoms (e.g., pressure, pain, fullness, bowel, or bladder symptoms), and has no desire for future fertility. In most cases, medical management should be trialed before pursuing more invasive therapies. The procedures are equivalent alternatives (i.e., only one procedure will be ordered to provide the clinical information to manage the patient's care effectively).
- Medical management or UAE is usually appropriate for the initial therapy in a patient who is of reproductive age, has UFs and concurrent AM, is symptomatic with heavy uterine bleeding or bulk symptoms (e.g., pressure, pain, fullness, bladder, or bowel symptoms), and has no desire for future fertility. In most cases, medical management should be trialed before pursuing more invasive therapies.
- Hysteroscopic MYO or medical management is usually appropriate for the initial therapy in a patient who is of reproductive age and has pedunculated submucosal UFs that are symptomatic with heavy uterine bleeding. In most cases, medical management should be trialed before pursuing more invasive therapies.
- Hysterectomy is usually appropriate as a next step for a postmenopausal patient who has UFs, is symptomatic with heavy uterine bleeding or bulk symptoms (e.g., pressure, pain, fullness, bladder, or bowel symptoms), and has a negative endometrial biopsy. These procedures are equivalent alternatives (i.e., only one procedure will be ordered to provide the clinical information to manage the patient's care effectively).
- Hysteroscopic MYO or laparoscopic or open MYO is usually appropriate for the initial therapy in a patient who is of reproductive age, has UFs, and is desiring pregnancy and experiencing reproductive dysfunction. These procedures are equivalent alternatives (i.e., only one procedure will be ordered to provide the clinical information to manage the patient's care effectively). The panel did not agree with recommending medical management for this clinical scenario. There is insufficient medical literature to conclude whether these patients would benefit from this procedure in this scenario. Intervention with this procedure in this patient population is controversial but may be appropriate.

National Institute for Health and Care Excellence (NICE)

The NICE guidelines on ultrasound-guided high-intensity transcutaneous focused ultrasound for symptomatic UFs state that the current evidence on the safety of ultrasound-guided high-intensity transcutaneous focused ultrasound for symptomatic UFs shows that there are well-recognized complications, including skin burns. The evidence on efficacy is limited in quality. Therefore, NICE recommends only using this procedure with special arrangements for clinical governance, consent, and audit or research. NICE recommends that:

- Clinicians wishing to do ultrasound-guided high-intensity transcutaneous focused ultrasound for symptomatic UFs should Inform the clinical governance leads in their National Health Service trusts.
- Ensure that individuals understand the procedure's safety and efficacy and any uncertainties about these, and provide them with clear written information to support shared decision-making. In addition, using NICE's information for the public is recommended.
- Audit and review clinical outcomes in all those having ultrasound-guided high-intensity transcutaneous focused ultrasound for symptomatic UFs. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

Additionally, NICE recommends that during the consent process, clinicians should tell patients that their symptoms may not be thoroughly relieved and may return and that further procedures may be needed. They should also inform patients about the risk of skin burns. Patients who are considering pregnancy should be told that the effects of the procedure on fertility and future pregnancy are uncertain. A multidisciplinary team, including a gynecologist and an appropriate imaging specialist, should do patient selection. The procedure should only be done in specialized centers by clinicians with specific training in this technique. NICE encourages further research and prospective data collection. Studies that compare US-HIFU with other therapies, such as UAE and magnetic resonance imaging–guided high-intensity transcutaneous focused ultrasound, would be helpful. Studies should report patient selection (including size, location, and number of fibroids), patient-reported outcome measures, long-term outcomes, and subsequent pregnancy rates (NICE, 2019).

A NICE guideline on the assessment and management of HMB recommends LNG-IUS as the first treatment for women with no identified pathology, fibroids less than 3 cm in diameter, or suspected or diagnosed AM. If the treatment is unsuccessful, the patient declines pharmacological treatment, or symptoms are severe, referral to a specialist is

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recommended to discuss additional options. For women with fibroids greater than 3 cm in diameter, LNG-IUS is listed as a pharmacological option (NICE, 2018; updated 2021).

The NICE guideline on the management of HMB lists UAE as an option for women with fibroids 3 cm or more in diameter. They recommend that the woman's uterus and fibroid(s) be assessed by ultrasound prior to the procedure, and if further information about fibroid position, size, number, and vascularity is needed, magnetic resonance imaging should be considered (NICE, 2018; updated 2021).

A NICE guidance document states that the current evidence on the efficacy of MRgFUS for UFs in the short term is adequate, although further treatment may be required, and the effect on subsequent pregnancy is uncertain. There are well-recognized complications, but the evidence on safety is adequate to support the use of this procedure, provided that normal arrangements are in place for clinical governance and audit. NICE encourages further research into the efficacy of MRgFUS for UFs. Research studies should report long-term outcomes, including the need for further treatment (NICE, 2011).

The NICE guidance document states that the current evidence on UAE for fibroids shows that the procedure is efficacious for symptom relief in the short and medium term in a substantial proportion of people. There are no major safety concerns. Therefore, this procedure may be used, provided that normal arrangements are in place for clinical governance and audit (NICE, 2010).

Society of Interventional Radiology (SIR)

SIR quality improvement guidelines (Dariushnia et al., 2014) state that UAE is indicated for the treatment of uterine leiomyomata that are causing significant symptoms, which are occasionally a single symptom but more commonly a combination of symptoms. The most common of these are:

- Heavy or prolonged menstrual bleeding
- Severe menstrual cramping
- Pelvic pressure, discomfort, excessive bloating, or fullness, particularly perimenstrual, or bothersome abdominal wall distortion caused by the enlarged uterus
- Pelvic pain related to identified leiomyomas, including dyspareunia
- Urinary urgency, frequency, nocturia, or retention related to the enlarged leiomyomatous uterus
- Hydronephrosis caused by the enlarged uterus

There is very low-level evidence suggesting that myomectomy may be associated with better fertility outcomes than UAE, but more research is needed. Therefore, in the absence of clear data to direct patient recommendations, the following approach is recommended:

- Each patient’s level of interest in pregnancy needs to be explored, particularly in relation to the patient’s age, previous interventions, pregnancies, and interest in assisted-reproductive technologies. For most patients, this should be coupled with an assessment of current fertility status, including evaluation by a reproductive endocrinologist if appropriate.
- For those patients without previous surgical interventions, with resectable leiomyomas, and with a reasonable likelihood of pregnancy based on other factors such as age, myomectomy may be preferred. However, given the weak evidence that favors myomectomy, patient preference for therapy should be respected, as long as the patient is well informed about our current knowledge of this issue.
- For those with previous myomectomy, there are no reproductive outcomes from high-quality studies, and, given the difficulty of repeat surgery, embolization may be preferred.
- The quality of the evidence to support the use of myomectomy to improve fertility is also very weak, without any data from randomized trials. Therefore, the uncertainty of outcomes from myomectomy should be included in the discussion with the patient.
- For those who are poor surgical candidates because of comorbidity, body habitus, or extent or location of leiomyomas, uterine embolization is an acceptable choice for those seeking to become pregnant.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Levonorgestrel-Releasing Intrauterine Device

Mirena received FDA approval on December 8, 2000, for use as an intrauterine contraceptive. Treatment of HMB for women who choose to use intrauterine contraception as their method of contraception was approved as an additional

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indication on October 1, 2009. Search the following website for more information: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. (AccessedJuly 9, 2026)

Skyla received FDA approval on January 9, 2013, for use as an intrauterine contraceptive. Search the following website for more information: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. (Accessed July 9, 2026)

Liletta received FDA approval on February 26, 2015, for use as an intrauterine contraceptive. Search the following website for more information: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. (Accessed July 9, 2026)

Kyleena received FDA approval on September 16, 2016, for use as an intrauterine contraceptive. Search the following website for more information: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. (Accessed July 9, 2026)

Uterine Artery Embolization

Uterine artery embolization is a procedure and therefore is not subject to FDA regulation. However, the embolic agents used are subject to FDA oversight. A number of agents are approved by the FDA for embolization procedures of the neurological system, but several have been specifically approved for uterine artery embolization. Search the following website for additional information: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. (Accessed July 9, 2026)

Magnetic Resonance–Guided Focused Ultrasound

The ExAblate 2000/2100 system (Insightec) received premarket approval on October 22, 2004 (P040003); approval for updated labeling was given on August 9, 2011. The device is indicated for ablation of uterine fibroid tissue in pre- or perimenopausal women with symptomatic uterine fibroids who desire a uterine-sparing procedure and whose uterine size is less than 24 weeks. On August 31, 2015, the indications were modified to remove the restriction of treatment to women who had completed childbearing. Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P040003S009. (Accessed July 9, 2026)

Laparoscopic Power Morcellation Warning

Laparoscopic power morcellators are Class II medical devices that are used during laparoscopic (minimally invasive) surgeries to cut tissue into smaller pieces so the tissue can be removed through a small incision site (typically 2 cm long or less). An FDA Safety Communication that was issued on November 24, 2014, recommends that manufacturers of laparoscopic power morcellators with a general indication or a specific gynecologic indication prominently include the following black box warning and contraindications in their product labeling:

- Warning
  - Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer and decrease the individual's long-term survival. Because of this risk and the availability of alternative surgical options for most women, the FDA is warning against the use of laparoscopic power morcellators in the majority of women undergoing myomectomy or hysterectomy for treatment of fibroids. This information should be shared with individuals when considering surgery with the use of these devices.
- Contraindications
  - Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.
  - Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in those who are peri- or postmenopausal or are candidates for en bloc tissue removal, i.e., through the vagina or via a minilaparotomy incision.

For FDA warnings, contraindications, final guidance, updates, and additional information, refer to the following website: https://www.fda.gov/medical-devices/surgery-devices/laparoscopic-power-morcellators. (Accessed July 9, 2026)

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Policy History/Revision Information

Date	Summary of Changes
11/01/2026	**Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version 2026T0442VV

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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