Abnormal Uterine Bleeding and Uterine Fibroids (for Louisiana Only)
Retired April 1, 2026

Policy Number: CS002LA.AB
Effective Date: January 1, 2026 – March 31, 2026

➲ Instructions for Use

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Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

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 (LNG-IUD) (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 (UAE) is proven and medically necessary for treating symptomatic uterine fibroids, postpartum or post hysterectomy bleeding, or uterine arteriovenous malformation (AVM). For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Uterine Artery Embolization (UAE).

Click here to view the InterQual® criteria.

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

Magnetic resonance-guided focused ultrasound ablation (MRgFUS) 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 federal, state, or contractual requirements, 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 services requested.

The patient's medical record must contain documentation that fully supports the medical necessity for the requested services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request.

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 federal, state, or contractual requirements 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

Codes labeled with an asterisk (*) are not on the State of Louisiana Medicaid Fee Schedule and therefore may not be covered by the State of Louisiana Medicaid Program.

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 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 conditions 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 Gynecologist (ACOG), fibroids are most commonly found in women aged 30-40 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 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 (LNG-IUD)

The local administration of the progestin levonorgestrel is delivered via an intrauterine device (IUD). 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 (UAE)

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

Magnetic Resonance-Guided Focused Ultrasound (MRgFUS)

This procedure combines real-time MR-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.

Clinical Evidence

Levonorgestrel-Releasing Intrauterine Device (LNG-IUD)

Zhang et al. 2025 conducted a systematic review and meta-analysis including 28 studies, of which 9 were randomized controlled trials (RCT) and 19 were non-RCTs to summarize the evidence on the efficacy and safety of the levonorgestrel-releasing intrauterine system (LNG-IUD) in managing adenomyosis (AM), both as a monotherapy and in combination with other therapies. The primary outcome measured was dysmenorrhea, menstrual bleeding, uterine volume, endometrial thickness, and quality of life. 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. Comparing LNG-IUS with mifepristone, there was no significant difference in terms of quality of life. The combination of LNG-IUS with Gonadotropin-releasing hormone agonists (GnRH-a) 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 surgical excision alone, providing benefits in reducing dysmenorrhea, menstrual bleeding at 12 months, reducing 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, menstrual bleeding. The authors concluded that for single-drug therapy intended on improving pain and quality of life, 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 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 presenting with severe symptoms receive LNG-IUS as soon as possible following the intervention. Though, more research with high quality is needed to further evaluate the effect and safety in more than 12 months.

As a long-term follow-up study of a multicenter RCT MIRA trial, Huijs et al. (2024) sought to assess the long-term differences in the reintervention risk and menstrual blood loss for 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 52-mg LNG-IUD (n = 132) or radiofrequency on resectoscopic endometrial ablation (n = 138). The outcomes measured were the reintervention rate, menstrual bleeding, quality of life (QOL), sexual function, and patient 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% (34/85) in the 52-mg LNG-IUS group and 28.7% (27/94) in the radiofrequency nonresectoscopic endometrial ablation group (relative risk, 1.39; 95% confidence interval (CI), 0.92-2.10). The cumulative rate of surgical reinterventions was only significantly higher among those with a treatment strategy starting with a 52-mg LNG-IUS compared with radiofrequency nonresectoscopic endometrial ablation [35.3% (30/85) vs 19.1% (18/94); relative risk, 1.84; 95% CI, 1.11-3.10]. However, the hysterectomy rate was similar [11.8% (10/94) in the 52-mg LNG-IUS group and 18.1% (17/102) 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 patient 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 Federation of Gynecology and Obstetrics (FIGO) 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 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 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 lower 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.

In a 2024 systematic review and single-arm meta-analysis, Oliveira and associates examined the LNG-IUS in women with inherited bleeding disorders and HMB. The exploration uncovered six observational studies (n = 156) that met 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 pre-treatment levels. The post-treatment mean hemoglobin was 13.32 g/dL, and the mean ferritin was 43.22 ng/dL. The rate of IUD 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, the small number of studies, and the 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 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 Gonadotropin-Releasing Hormone Agonist (GnRH-a) or LNG-IUS for people with AM. The outcomes measured were the treatment efficacy rate of dysmenorrhea, the effective rate of menorrhagia severity, and the reduction rate of AM lesion. Adverse events were also assessed. The results uncovered that HIFU plus LNG-IUS showed lower dysmenorrhea [within six months: risk ratio (RR) 0.88, 95% CI 0.83-0.93, $p < 0.00001$; over one 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 showed 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 included 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 than that of HIFU and GnRH-a.

Chen et al. (2022) compares the safety and efficacy of the LNG-IUS with other medical treatments for women with HMB. A search was conducted using Cochrane Central Register of Controlled Trials (CENTRAL), PubMed, Embase, and Wanfang databases. A total of thirteen RCTs were retrieved for the systematic review and twelve were included for meta-analyses. A total of 1,677 individuals were included with the average age ranging from 28 to almost 42 years of age and all 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 of 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 assessed was clinical response to treatment and secondary outcomes included menstrual blood loss, QOL, adverse events, and patient satisfaction. The Cochrane Risk of Bias Tool was used for assessment for the risk of bias for the included RCTs. The authors found that the number of clinical responders was greater in the LNG-IUS group than that of 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, compliance, and satisfaction when compared to that of medical treatments. Limitations included lack of long-term data, high risk of performance bias due to the blinding of participants and personnel, and self-reported data.

Evidence from a Cochrane Systematic Database Review by Bofill Rodriguez et al. (2022) suggests 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 patient characteristics, including the desire for future pregnancy, failure of previous treatment or having been referred for surgery. The data analyzed included 9,950 participants 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 to a sham treatment. Surgical interventions included open, minimally invasive and unspecified routes for hysterectomy, resectoscopic endometrial ablation, non-resectoscopic endometrial ablation and unspecified endometrial ablation. In non-surgical 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 it to different combined hormonal contraceptives for 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 for women with HMB when compared to other medical treatments or placebos; the authors' conclusion was 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 included the small number of participants in the differing trials and a high-risk of bias for blinding.

Cim et al. (2018) reported two-year follow-up data of people with AUB after insertion of the LNG-IUS. One hundred and six parous women aged 33-48 years with recurrent HMB participated in this study, and were followed for 1, 3, 6, 12, 18, and 24 months following the insertion. The authors reported that all women well tolerated the LNG-IUS. Pre-treatment of the use of the LNG-IUS, endometrial biopsy patterns for irregular proliferative endometrium and for atypical simple hyperplasia were 34/106 (32.08%) and 61/106 (57.55%) respectively and after treatment no abnormal pathologic 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 (QALYs), and probabilistic sensitivity analysis. The LNG-IUS had the highest number of QALYs (406, 920), followed by hysterectomy (403, 466), non-resectoscopic 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.

A Cochrane review (Marjoribanks et al., 2016) compared the effectiveness, safety, and acceptability of surgery versus medical therapy for HMB. Fifteen RCTs (n = 1,289) comparing surgery versus oral medication or LNG-IUD for treating HMB were included. The authors concluded that hysterectomy, endometrial surgery, and the LNG-IUD were all effective in reducing HMB, though surgery was most effective, at least over the short term. These treatments suited most women better than oral medication. Although hysterectomy will stop HMB, it is associated with serious complications. Both conservative surgery and LNG-IUD appear to be safe, acceptable, and effective.

An updated Cochrane systematic review by Lethaby et al. (2015) evaluated the safety and efficacy of the LNG-IUD for HMB. Twenty-one RCTs in women of reproductive age treated with progesterone or progestogen-releasing intrauterine

devices versus no treatment, placebo or other medical or surgical therapy for HMB were included. The authors concluded that the LNG-IUD is more effective than oral medication as a treatment for HMB. The device is associated with a greater reduction in HMB, improved QOL and appears to be more acceptable long term but is associated with more minor adverse effects than oral therapy. When compared to endometrial ablation, it is not clear whether the LNG-IUD offers any benefits regarding reduced HMB, and satisfaction rates and QOL measures were similar. Limitations included inconsistency and inadequate reporting of study methods.

In a systematic review of twenty-six studies, Matteson et al. (2013) compared the effectiveness of nonsurgical AUB treatments for bleeding control, QOL, pain, sexual health, patient satisfaction, additional treatments needed and adverse events. Interventions included the levonorgestrel intrauterine system, combined oral contraceptive pills (OCPs), progestins, NSAIDs and antifibrinolytics. For reduction of menstrual bleeding in women with AUB presumed secondary to endometrial dysfunction, the levonorgestrel intrauterine system (71-95% reduction), combined OCPs (35-69% reduction), extended cycle oral progestins (87% reduction), tranexamic acid (26-54% reduction) and NSAIDs (10-52% reduction) were all effective treatments. The levonorgestrel intrauterine system, combined OCPs and antifibrinolytics, were all superior to luteal phase progestins (20% increase in bleeding to 67% reduction). The levonorgestrel intrauterine system was superior to combined OCPs and NSAIDs. Antifibrinolytics were superior to NSAIDs for menstrual bleeding reduction. Data were limited on other important outcomes such as QOL for women with AUB presumed secondary to endometrial dysfunction and for all outcomes for women with AUB presumed secondary to ovulatory dysfunction.

In another systematic review, Matteson et al. (2012) compared hysterectomy with less-invasive alternatives for AUB. Nine RCTs comparing bleeding, QOL, pain, sexual health, satisfaction, need for subsequent surgery and adverse events were included. Endometrial ablation, levonorgestrel intrauterine system and medications were associated with lower risk of adverse events but higher risk of additional treatments than hysterectomy. Compared to ablation, hysterectomy had superior long-term pain and bleeding control. Compared with the levonorgestrel intrauterine system, hysterectomy had superior control of bleeding. No other differences between treatments were found. The review group concluded that less-invasive treatment options for AUB result in improvement in QOL but carry significant risk of retreatment caused by unsatisfactory results. Although hysterectomy is the most effective treatment for AUB, it carries the highest risk for adverse events.

Uterine Artery Embolization (UAE)

There is insufficient evidence to conclude that the treatment of fibroids with UAE preserves childbearing potential. Most studies on UAE's impact on fertility are low quality and small sample size limiting 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 involving larger, robust RCT's is needed to establish safety, effectiveness, and long-term outcomes.

Peng et al. 2024 conducted a systematic review and meta-analysis of current evidence comparing the efficacy of uterine UAE versus myomectomy (MYO) for managing symptomatic uterine fibroids (UFs) in women opposed to undergoing a hysterectomy. A meta-analysis was completed on all available studies that assessed the relative benefits and harms of MYO and UEA for managing individuals suffering from UFs. The outcomes evaluated were reintervention, UFs scores for QOL and symptom severity, along with other complications. The results of the meta-analysis showed that UAE had a higher reintervention rate, hysterectomy rate, and symptom-severity score compared to MYO at a four-year follow-up. However, UAE was associated with a lower rate of early complications, and readmission rate, compared to MYO. Additionally, both procedures had similar improvement in pregnancy rates and abnormal uterine bleeding. The limitations of the study included 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 patient groups. Lastly, the outcomes were inconsistent among papers, limiting the quantity of articles to synthesize, potentially introducing selection bias. The authors concluded that UAE and MYO are effective in treating symptomatic UFs, but 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 and associates conducted a systematic review with trial sequential analysis aimed at focusing on pregnancy rate and outcomes for females after UAE. A subgroup analysis was also performed based on different patient populations or various control treatments. The overall results revealed that UAE significantly decreased postoperative pregnancy rate [RR (95% CI): 0.721 0.531−0.979], 95% PI: 0.248−2.0970 and was associated with an increased risk of postoperative postpartum hemorrhage (PPH) [RR (95% CI): 3.182 (1.319−7.675), 95% PI: 0.474−22.089]. Analysis grouped by population indicated that UAE decreased the risk of preterm delivery [RR (95% CI): 0.326 (0.128−0.831), p = 0.019] and cesarean section [RR (95% CI): 0.693 (0.481−0.999), p = 0.050] and increased the risk of placenta previa [RR (95% CI): 8.739 (1.580−48.341), p = 0.0130] in those with UFs, cesarean scar pregnancy (CSP), and PPH, respectively. When compared with MYO, HIFU, and non-use of UAE, UAE treatment was associated with the reduced risks of preterm

delivery [RR (95% CI): 0.296 (0.106−0.826)] and cesarean section [(95% CI): 0.693 (0.481−0.999), p = 0.050] and increased placenta previa risk [RR (95% CI): 10.682 (6.859−16.636)], respectively. Limitations of the study include heterogeneity, lack of specificity whether the participants in the research suggested exclusively from a single disease, and an insufficient number of studies to continue sub-analysis 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 suggested 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, USgHIFU and MRgHIFU, and transcervical radiofrequency ablation (TFA) procedures. A search using PubMed, Google Scholar, ScienceDirect, Cochrane Library, Scopus, Web of Science and Embase were performed and returned 25 articles. The number of pregnancies varied considerably amongst the studies, as well as the mean age of the women which usually included women > 40 years of age. The rates of live births for UAE, HIFU, and TFA were similar at 70.8%, 73.5%, and 70%, respectively. Miscarriage rate was the greatest in the UAE group which accounted for 19.2%. Overall, the delivery rate by cesarean section was greater in these minimally invasive procedures when compared to that for the general population rate (31.8%); this was most likely due to the greater risks associated with women with UFs. Upon analysis, the authors found the estimation of pregnancy was found to be higher after UAE and HIFU when compared to 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 versus another. Limitations included 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 post-procedure fertility outcomes. A search of the literature was performed using PubMed/Medline, Google scholar, Cochrane, and EMBASE databases. The search resulted in seventeen articles for review: two RCTs, two prospective controlled studies, seven prospective cohorts, four retrospective cohorts and three case series. One key factor identified during the research was the age of the participants and the effect on fertility; studies that included women over the age of forty had a negative impact on fertility. However, the overall mean age was 35.9 years thus the authors suggested 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 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 where UAE treatment of premenopausal women was performed for UFs with and where a control intervention was included. The PRISMA guideline was used to do a systematic review using the main outcomes pregnancy rate and miscarriage rate. Risk of bias was assessed by the Cochrane risk of bias tool or by ROBINS-I. The quality of evidence was assessed by the GRADE approach. 17 studies comprising 989 patients were selected and included 1 RCT, 2 cohort studies, and 14 case series. The results showed 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%. Miscarriage rates were 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 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 (AHRQ) published a comparative effectiveness review on 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 safety of the UAE on reproductive outcomes. Additionally, the uncertainty in estimates of leiomyosarcoma prevalence and evolving data about methods for tissue extraction requires exploration (Hartmann et al., 2017).

Magnetic Resonance-Guided Focused Ultrasound Ablation (MRgFUS)

There is insufficient evidence to conclude that MRgFUS 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 involving larger, robust RCTs is needed to establish its safety, efficacy, and long-term outcomes.

In a 2024 systematic review and meta-analysis, Dou and associates 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 treated with HIFU. There were 3,247-, 1,239-, 1,762-, and 2,535-women 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 of those treated with US-guided HIFU (USgHIFU) were significantly lower than those treated with MRgFUS. When the non-perfused 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-/iso-intensity fibroids on T2WI was 3.45 times higher (95% CI: 2.7-4.39) for hypo-/iso-intensity fibroids. The limitations of the study include the inclusion of several observation studies due to 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 USgHIFU, NPVR ≥ 50%, and iso-intensity of fibroids on T2WI were significant factors in reducing intervention.

Through a systematic review and meta-analysis, Hu, and colleagues (2023) compared high-intensity focused ultrasound and laparoscopic treatment of UFs. A total of 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 higher rates of miscarriage or postpartum complications than women who underwent laparoscopic MYO. Limitations of the study included 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 with fertility requirements.

Kociuba et al. (2023) evaluated the most common adverse events (AEs) and complications in people following MRgFUS therapy for UFs. A literature search using PubMed/MEDLINE, Scopus and CENTRAL returned forty-three publications for analysis which totaled 3,102 participants; most studies were cohorts with only two RCTs. Overall, the risk bias assessment categorized 23 studies as low, 8 studies as moderate, and 12 studies as high risk of bias based on the reported AEs. 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 AEs. Sonalleve was the second most popular device found in eleven studies with a mean occurrence of 40.3% for AEs. Pain (pelvic/abdominal) was the most common reported AE 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 uterine fibroid therapy with the occurrence of AEs as rather low in addition to very few major AEs identified. However, the authors did find nerve damage as another clinical problem that should be considered as a potentially serious AE for a patient when performing MRgFUS. Limitations included small sample size with short follow-up time, lack of pain assessment tools, and unclear definition of an AE. Future prospective RCTs on 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 the evidence may be somewhat favorable based on review of five systematic reviews with meta-analysis. Evidence assessment included results for symptom relief, QOL, reintervention rate, hospital stay, recovery time, post procedure pregnancy rate, and adverse events. When compared to surgery, HIFU was associated with fewer adverse events, shorter hospital stays, and a better QOL after one year. When compared to 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 magnetic resonance-guided focused ultrasound (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 magnetic resonance-guided high intensity focused ultrasound (MR-HIFU) and ultrasound-guided HIFU. Forty-eight studies were included for review; twenty-eight addressed the MR-HIFU and 20 focused on US-HIFU. UFs with of a volume of < 300 cm3 were part of the inclusion criteria. NPVR is considered a significant parameter that is positively connected with clinical success rate. A NPVR for the MR-HIFU was 58.92% which was lower than that of the US-HIFU group which was 81.07%. A NPVR of greater than 80% is 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 treatment of symptomatic UFs, the author’s conclusions revealed the US

procedure had greater safety and efficacy than the MR procedure. Limitations included 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 (FUS), and RFA. Eighty-one relevant papers were identified: 52 related to UAE, 11 to RFA, 17 to FUS, 1 compared UAE and FUS. Uterine volume and fibroid volume changes seen in these studies were at 1 to 36 months. The pooled fibroid volume reductions at six months seen with RFA were 70%, UAE 54% and FUS 32%. All three types of non-respective treatment result in fibroid volume reduction. However, fibroid volume reduction is 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 endpoint was to investigate the feasibility, and safety of the technique. Six articles containing 541 individuals were evaluated and no major complications of the procedure were found. After reviewing the data, the authors concluded microwave ablation of UFs to be safe and effective, however, larger randomized prospective trials are needed to better demonstrate the benefits. The authors found 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 report and Kociuba et al. 2023 systematic review above) conducted a RCT and comprehensive cohort analysis to compare the periprocedural outcomes of fibroid embolization and focused ultrasound. Premenopausal women with symptomatic UFs seen at three US academic medical centers were enrolled in the RCT (n = 57). Women meeting identical criteria who 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 undergoing focused ultrasound and UAE received the same post procedure 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 post procedure 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 focused ultrasound surgery was a longer procedure than embolization, with 23 (over half) women undergoing focused ultrasound 2 treatment days. Immediate self-rated post procedure pain was higher after UAE than focused ultrasound. Compared with those having focused ultrasound (n = 39), women undergoing embolization (n = 36) were more likely to use outpatient opioid (75% vs. 21%) and nonsteroidal anti-inflammatory medications (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 uterine fibroid 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, patient eligibility with numerous exclusion criteria and restrictive selection criteria and concluded that more comparative trials are needed to assess MRgFUS against other more established uterine-preserving treatments.

In a clinical assessment, ECRI concluded the evidence for the ExAblate Body System was inconclusive. The evidence suggests that the ExAblate reduces symptoms and improves the QOL in women up to three 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 small sample size, retrospective design, high patient attrition, lack of control groups, randomization, and blinding. (ECRI 2017; updated August 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 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 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 failed to respond 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 (LNG-IUD)

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

An ACOG practice bulletin on the use of non-contraceptive uses of hormonal contraceptives says the following:

- Combined oral contraceptives (OC) 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 (ACOG, 2010; reaffirmed 2020). (Evidence Level B – Based on limited or inconsistent scientific evidence).

Magnetic Resonance Imaging-Guided Focused Ultrasound Ablation

In a practice bulletin on management of symptomatic uterine leiomyomas ACOG states that while limited, low quality data suggests MRgFUS is associated with a reduction in leiomyoma and uterine size, smaller randomized comparative data suggests 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 (UAE)

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

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

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 of a reproductive age patient with UFs, symptomatic with heavy uterine bleeding or bulk symptoms (e.g., pressure, pain, fullness, bladder, or bowel symptoms), and 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 for a reproductive age patient with UFs, symptomatic with heavy uterine bleeding or bulk symptoms (e.g., pressure, pain, fullness, bowel, or bladder symptoms), and no desire for future ACR Appropriateness Criteria® 15 Management of Uterine Fibroids 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 for a reproductive-age patient with UFs and concurrent AM, symptomatic with heavy uterine bleeding or bulk symptoms (e.g., pressure, pain, fullness, bladder, or

bowel symptoms), and 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 for a reproductive-age patient with 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 with UFs, symptomatic with heavy uterine bleeding or bulk symptoms (e.g., pressure, pain, fullness, bladder, or bowel symptoms) and 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 for a reproductive-age patient with UFs 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 individuals would benefit from this procedure in this scenario. Intervention with this procedure in this patient population is controversial but may be appropriate.

National Institute of 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 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 NHS 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 of 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 individuals 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. Individuals 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 comparing ultrasound-guided high-intensity focused ultrasound with other therapies, such as UAE and MRI-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 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 recommended to discuss additional options. For women with fibroids greater than 3 cm in diameter, LNG-IUS is listed as a pharmacologic 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, MRI should be considered (NICE, 2018; updated 2021).

A NICE guidance document states that 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 current evidence on UAE for fibroids shows that the procedure is efficacious for symptom relief in the short and medium term for 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, 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

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 (LNG-IUD)

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 indication on October 1, 2009. Search the following website for more information: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. (Accessed June 23, 2025)

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 June 23, 2025)

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 June 23, 2025)

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 June 23, 2025)

Uterine Artery Embolization (UAE)

UAE is a procedure and, therefore, 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 UAE. Search the following website for additional information: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. (Accessed June 23, 2025)

Magnetic Resonance-Guided Focused Ultrasound (MRgFUS)

The ExAblate 2000/2100 System (Insightec) received premarket approval (PMA) 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 June 23, 2025)

Laparoscopic Power Morcellation Warning

Laparoscopic power morcellators are Class II medical devices 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 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 post-menopausal, or are candidates for en bloc tissue removal, for example through the vagina or via a mini-laparotomy 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 June 23, 2025)

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Policy History/Revision Information

Date	Summary of Changes
04/01/2026	• Retired policy; Louisiana plan membership disenrolled on Apr. 1, 2026

01/01/2026	**Medical Records Documentation Used for Reviews**
	• Added language to indicate:
	  ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, 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
	  ○ The patient's medical record must contain documentation that fully supports the medical necessity for the requested services
	  ○ This documentation includes but is not limited to relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures
	  ○ Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request
	Supporting Information
	• Updated *Clinical Evidence* and *References* sections to reflect the most current information
	• Archived previous policy version CS002LA.AA

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, check the federal, state or contractual requirements for benefit plan coverage. 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.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.