Abnormal Uterine Bleeding and Uterine Fibroids (for Indiana Only)

Policy Number: CS002IN.02
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Instructions for Use

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Related Policy

- Hysterectomy

Application

This Medical Policy only applies to the state of Indiana.

Coverage Rationale

See Benefit Considerations

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 when there is documentation of evaluation of abnormal uterine bleeding (AUB) including endometrial biopsy for individuals > 40 years of age and a pap smear screening consistent with current guidelines. For medical necessity clinical coverage criteria, refer to the InterQual® 2021, Apr. 2021 Release, 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 women with symptomatic uterine fibroids due to insufficient evidence of efficacy.

The following procedures are unproven and not medically necessary for treating uterine fibroids due to insufficient evidence of efficacy:

- Magnetic resonance-guided focused ultrasound ablation (MRgFUS)

- Ultrasound-guided radiofrequency ablation (e.g., Acessa™, Sonata®)

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
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency
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
58578	Unlisted laparoscopy procedure, uterus
58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency
58999	Unlisted procedure, female genital system (nonobstetrical)

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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

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.

Ultrasound-Guided Radiofrequency Ablation

- Laparoscopic Ultrasound-Guided Radiofrequency Ablation: This minimally invasive procedure uses a laparoscopic ultrasound probe to determine the location and size of fibroids. Then a small electrode array delivers radiofrequency energy to destroy the fibroids.
- Transcervical Ultrasound-Guided Radiofrequency Ablation: This minimally invasive procedure destroys fibroids using a transcervical radiofrequency ablation device under integrated, real-time, intrauterine ultrasound imaging guidance.

Benefit Considerations

Some plan documents exclude benefit coverage for contraception. In those plan documents, coverage for intrauterine devices (IUD), including the levonorgestrel-releasing intrauterine device (LNG-IUD), is excluded when used for contraceptive purposes. However, in those plan documents, coverage exists for the levonorgestrel-releasing intrauterine device (LNG-IUD) when used for a non-contraceptive purpose, including treatment of abnormal uterine bleeding, when supported by clinical evidence.

Most plan documents provide coverage for unproven services for a life-threatening sickness or condition, at our discretion. Additionally, some plan documents may provide coverage for unproven services under certain non-life- threatening conditions at our discretion. Magnetic resonance-guided focused ultrasound (MRgFUS) is a covered service for certain benefit plans. Other terms and conditions to claims payment may apply, depending on the terms of the member specific benefit plan document, a provider's participation agreement and the UnitedHealthcare Administrative Guide.

Clinical Evidence

Levonorgestrel-Releasing Intrauterine Device (LNG-IUD)

Cim et al. (2018) reported two-year follow-up data of patients with abnormal uterine bleeding (AUB) after insertion of the levonorgestrel-releasing intrauterine system (LNG-IUS). One hundred and six parous women aged 33-48 years with recurrent heavy menstrual bleeding (HMB) participated in this study, and were followed for 1, 3, 6, 12, 18, and 24 months following the insertion. The authors reported that the LNG-IUS was well tolerated by all women. 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, 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 heavy menstrual bleeding. Fifteen randomized controlled trials (n=1289) comparing surgery versus oral medication or LNG-IUD for treating heavy menstrual bleeding were included. The authors concluded that hysterectomy, endometrial surgery and the LNG-IUD were all effective in reducing heavy menstrual bleeding, though surgery was most effective, at least over the short term. These treatments suited most women better than oral medication. Although hysterectomy will stop heavy menstrual bleeding, 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 heavy menstrual bleeding (HMB). Twenty-one randomized controlled trials in women of reproductive age treated with progesterone or progestogen-releasing intrauterine devices versus no treatment, placebo or other medical or surgical therapy for heavy menstrual bleeding 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 quality of life 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 with regard to reduced HMB, and satisfaction rates and quality of life 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 abnormal uterine bleeding treatments for bleeding control, quality of life (QOL), pain, sexual health, patient satisfaction, additional treatments needed and adverse events. Interventions included the levonorgestrel intrauterine system, combined oral contraceptive pills (OCPs), progestins, nonsteroidal anti-inflammatory drugs (NSAIDs) and antifibrinolytics. For reduction of menstrual bleeding in women with abnormal uterine bleeding 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 abnormal uterine bleeding presumed secondary to endometrial dysfunction and for all outcomes for women with abnormal uterine bleeding presumed secondary to ovulatory dysfunction.

In another systematic review, Matteson et al. (2012) compared hysterectomy with less-invasive alternatives for abnormal uterine bleeding (AUB). Nine randomized controlled trials comparing bleeding, quality of life, 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 quality of life 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.

Kaunitz et al. (2010) compared the efficacy and safety of the levonorgestrel-releasing intrauterine system and oral medroxyprogesterone acetate in the treatment of idiopathic heavy menstrual bleeding. In this multicenter, randomized, controlled study, women aged 18 years or older with heavy menstrual bleeding (menstrual blood loss 80 mL or more per cycle) were randomly assigned to six cycles of treatment with either levonorgestrel-releasing intrauterine system or oral medroxyprogesterone acetate. Of 807 women screened, 165 were randomly assigned to treatment (levonorgestrel-releasing intrauterine system n=82, oral medroxyprogesterone acetate n=83). At the end of the study, the absolute reduction in median menstrual blood loss was significantly greater in the levonorgestrel-releasing intrauterine system group than in the medroxyprogesterone acetate arm, and the proportion of women with successful treatment was significantly higher for the levonorgestrel-releasing intrauterine system (84.8%) than for medroxyprogesterone acetate (22.2%).

Kaunitz et al. (2009) compared the effects of the levonorgestrel intrauterine system and endometrial ablation in reducing heavy menstrual bleeding. The systematic review and meta-analysis were restricted to randomized controlled trials in which menstrual blood loss was reported using pictorial blood loss assessment chart scores. Six randomized controlled trials that included 390 women (levonorgestrel intrauterine system, n=196; endometrial ablation, n=194) were reviewed. Three studies pertained to first-generation endometrial ablation (manual hysteroscopy) and three to second-generation endometrial ablation (thermal balloon). Both treatment modalities were associated with similar reductions in menstrual blood loss after 6 months, 12 months and 24 months. In addition, both treatments were generally associated with similar improvements in quality of life in five studies that reported this as an outcome. No major complications occurred with either treatment modality in these small trials. The authors concluded that the efficacy of the levonorgestrel intrauterine system in the management of heavy menstrual bleeding appears to have similar therapeutic effects to that of endometrial ablation up to 2 years after treatment.

A National Institute of Health and Care Excellence (NICE) guideline on assessment and management of heavy menstrual bleeding recommends LNG-IUS as the first treatment for women with no identified pathology, fibroids less than 3 cm in diameter, or suspected or diagnosed adenomyosis. 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, 2020)

Magnetic Resonance-Guided Focused Ultrasound Ablation (MRgFUS)

A Hayes report 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 focused ultrasound ablation of uterine fibroids on symptoms and the comparative effectiveness with other treatment alternatives. (Hayes, 2019)

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 quality of life (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.

In a 2019 systematic review (included in Hayes report), Taheri et al. examined the change in uterine and fibroid volumes associated with uterine artery embolization (UAE), focused ultrasound (FUS), and radiofrequency ablation (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 nonresective 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.

Verpalen et al. (2019, included in ECRI report) reassessed the effectiveness of Magnetic Resonance-High Intensity Focused Ultrasound (MRHIFU) on reducing fibroid related symptoms. Patients with fibroids containing a high T2 signal intensity or Funaki type 3 were excluded. Eighteen articles were included for review; sixteen of them were clinical trials and all were case series. The quality of evidence ranged from 9 to 16 using the 18-point criteria tool. The level of evidence for all included studies was IV according to Oxford Centre for Evidence-based Medicine (OCEBM) guidelines. Only 6 of the 18 studies were of acceptable quality. The author's concluded all studies displayed fibroid shrinkage and demonstrated that fibroids could continue shrink up to a years' time following the procedure. Adverse events were minimal and only two patients experience a serious adverse effect (DVT and third-degree skin burn). The studies suggested that MRHIFU may be a cost-effective strategy however the topic of cost was not analyzed. Limitations included weaknesses of a meta-analysis design, potential high-risk bias related to specific study designs, different sample sizes and loss of follow-up in some sub-studies. The authors expressed additional future studies are needed, but because randomized trials are difficult to conduct and pose methodological challenges along with difficulty recruiting patients, larger comparative controlled cohort studies with longer follow-up are warranted.

Ierardi et al. (2018) performed a systematic review for percutaneous ablation on uterine fibroids. The primary endpoint was to investigate feasibility and safety of the technique. Six articles containing 541 patients was evaluated and no major complications of the procedure was found. After reviewing the data, the authors concluded microwave ablation of uterine fibroids 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 ECRI and Hayes reports) conducted a randomized controlled trial and comprehensive cohort analysis to compare the periprocedural outcomes of fibroid embolization and focused ultrasound. Premenopausal women with symptomatic uterine fibroids seen at 3 US academic medical centers were enrolled in the randomized controlled trial (n = 57). Women meeting identical criteria who declined randomization but agreed to study participation were enrolled in a nonrandomized parallel cohort (n = 34). The 2 treatment groups were analyzed by using a comprehensive cohort design. All women undergoing focused ultrasound and uterine artery embolization 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 uterine artery embolization 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, uterine artery embolization 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 randomized controlled trial. 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.

Havryliuk et al. (2017, included in Hayes report) conducted a systematic review and meta-analysis from clinical studies that described populations of pre-menopausal women seeking surgical management (both uterine-sparing and hysterectomy) for their symptomatic fibroids. Procedures included in the analysis were myomectomy, UAE, Lap-RFA, MRg-FUS, and hysterectomy. The complication rate for MRg-FUS was 6.0% (1.3% major; 5.1% minor) (N=298), and long-term follow-up averaged 12.6 months (N=209). The reintervention rate was highest of all the procedures at 30.5% (145 combined patients). Based on their analysis, the authors concluded that MRg-FUS carries low complication rates, no blood loss, and moderate improvement in HRQL scores. However, there is also a significant concern for injury of organs that may be in the way for focused ultrasound such as bowel, bladder, and sacral nerves. The authors state that limitations of this review include the inherent heterogeneity among studies; only a portion of the included studies were randomized controlled trials, most were not and were assigned an ACOG quality score of B; and lack of uniformity in reporting conventions. Further comprehensive prospective research, ideally in the form of well-powered randomized controlled trials, is needed to validate the specific treatment modality preferred for specific anatomical variances of fibroids.

In a pilot study (PROMISe), Jacoby et al. (2016, included in Hayes report) assessed the feasibility of a full-scale, randomized, placebo-controlled trial to evaluate the safety and efficacy of MRgFUS in premenopausal women with symptomatic uterine fibroids. Twenty women (mean 44 years of age) were enrolled. Thirteen were randomly assigned to MRgFUS and 7 to sham therapy. The primary outcome was a change in fibroid symptoms from baseline to 4 and 12 weeks after treatment assessed by the Uterine Fibroid Symptom Quality of Life Questionnaire (UFS-QOL). Secondary outcome was incidence of surgery or procedures for recurrent symptoms at 12 and 24 months. Four weeks after treatment, all participants reported improvement in the UFS-QOL: a mean of 10 points in the MRgFUS group and 9 points in the placebo group. By 12 weeks, the MRgFUS group had improved more than the placebo group (mean 31 points and 13 points, respectively). The mean fibroid volume decreased 18% in the MRgFUS group with no decrease in the placebo group at 12 weeks. After unblinding at 12 weeks, 5 patients in the sham group opted for treatment by MRgFUS and were followed for an additional 12 weeks. Two years after MRgFUS, 4 of 12 women who had a follow-up evaluation (30%) had undergone another fibroid surgery or procedure. The authors noted that a placebo effect may explain some of the improvement in fibroid-related symptoms observed in the first 12 weeks after MRgFUS. This study is limited by very small sample size and substantial loss to follow-up.

In a nonrandomized clinical trial, Froeling et al. (2013, included in Hayes report) compared the long-term outcome after uterine artery embolization (UAE) (n=41) versus magnetic resonance-guided high-intensity focused ultrasound (MR-g HIFU) (n=36) in women with symptomatic uterine fibroids. Symptom severity and total health-related quality of life scores were assessed by questionnaire before treatment and at long-term follow-up after UAE (median 61.9 months) and after MR-g HIFU (median: 60.7 months). Reintervention was significantly lower after UAE (12.2%) than after MR-g HIFU (66.7%) at long-term follow-up. The authors reported that improvement of symptom severity and health-related quality of life scores was significantly better after UAE resulting in a significant lower reintervention rate compared to MR-g HIFU.

In a prospective cohort study, Dobrotwir and Pun (2012) evaluated the efficacy and safety of MRgFUS in 100 patients (mean age 42 years) with symptomatic fibroids (n=104 treatments). Mean pretreatment fibroid volume was 185 cm^3 (range 2 to 1109). The authors reported that fibroid volume significantly decreased by the 12-month follow-up, and that the symptom severity score decreased by 55%. However, 14% of these patients required reintervention for persistent or recurrent fibroid disease. This study is limited by lack of randomization and control and short-term follow-up.

A retrospective study of 130 patients with symptomatic uterine leiomyomas treated with MRgFUS reported that the cumulative incidence of subsequent treatments for leiomyomas, such as hysterectomy or myomectomy, was 7.4% at 12-months. Patients were followed through retrospective review of medical records and phone interviews. At 3-, 6- and 12-month follow-up, 86% (90 of 105), 93% (92 of 99), and 88% (78 of 89) of patients reported relief of symptoms, respectively. Treatment-related

complications were observed in 17 patients (13.1%): 16 patients had minor complications and one had a major complication (deep vein thrombosis). All complications were resolved within the 12-month follow-up period. This study is limited by its retrospective design (Gorny et al., 2011).

According to a systematic review prepared for the AHRQ, high intensity focused ultrasound reduced fibroid and uterine size, but strength of evidence is low because of short followup and poor quality of overall study design. Evidence related to patient reported outcomes is insufficient (Hartmann et al., 2017, included in Hayes report).

A National Institute for Health and Care Excellence (NICE) guidance document states that current evidence on the efficacy of MRgFUS for uterine fibroids 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 uterine fibroids. Research studies should report long-term outcomes, including the need for further treatment (NICE, 2011).

Ultrasound-Guided Radiofrequency Ablation Procedures

There is insufficient evidence to conclude laparoscopic or transcervical ultrasound-guided radiofrequency ablation procedures are effective for the treatment of fibroids. The body of evidence is low and additional research involving larger, randomized control trials is needed to establish their safety, efficacy and long-term outcomes.

Bradley et al. (2019) performed a systematic review and meta-analysis for treatment of fibroids with radiofrequency ablation (RFA). The authors identified 32 articles which included 1283 patients that were treated with either laparoscopic, transvaginal or transcervical RFA. It was hypothesized that RFA would significantly reduce fibroid volume and improve the patient's quality of life. The authors found that transcervical and transvaginal ablation were associated with a shorter length of stay on average and transcervical RFA had a faster return to normal activities when compared to laparoscopic RFA. Main strengths of the review included adherence to PRISMA guidelines, inclusion of almost 1300 patients and excellent generalization of results. The authors concluded that RFA was effective for symptomatic uterine fibroids and improved the quality of life for patients. Limitations included lack of long-term data after 12 months, insufficient number of studies to perform statistical comparison among RFA delivery approaches and inability to determine if RFA efficacy was influenced by fibroid type or volume.

Laparoscopic Ultrasound-Guided Radiofrequency Ablation

A Hayes report evaluated the safety and efficacy of the Acessa System for treating uterine fibroids. Overall, a low-quality, limited body of evidence suggests that radiofrequency volumetric thermal ablation (RFVTA) consistently reduces the symptoms of uterine fibroids and improves health-related quality of life; however, substantial uncertainty exists regarding the comparative effectiveness and continued durability of this treatment. Limitations of the studies include small sample size, lack of a control group, limited follow-up and substantial attrition (Hayes, 2019).

An ECRI custom product brief regarding the Acessa™ system (Acessa Health, Inc.) concluded that limited evidence suggests that radiofrequency volumetric thermal ablation (RFVTA) improves symptoms and quality of life (QOL), and very limited evidence suggests that RFVTA offers minimally invasive, fertility-sparing uterine fibroid treatment. More randomized controlled trials (RCTs) are needed to elucidate RFVTA's best use (ECRI 2018).

Lin et al. (2019) conducted a meta-analysis assessing the short-term (3 and 6 months) and long-term (12, 24, and 36 months) symptom relief and quality of life improvement, procedure-related adverse event rate, reintervention rate, and days missed from work after laparoscopic radiofrequency ablation. Eight studies with a total of 581 patients were included in this review. Based on validated questionnaires, quality of life improved significantly until 36 months after laparoscopic radiofrequency ablation therapy, with a maximum improvement (Health-Related Quality of Life [HRQL] questionnaire score of +41.64 [95% confidence interval (CI), 38.94-44.34] and a transformed Symptom Severity Score [tSSS] of -39.37 [95% CI, 34.70-44.04]) at 12 months after laparoscopic radiofrequency ablation. All subscales of quality of life improved significantly, and most of the changes remained stable in long-term follow-up. The overall reintervention rate was 4.39% (95% CI, 1.60%-8.45%), and the median uterine volume reduction was 69.17 cm^3 (95% CI, 35.87-102.46 cm^3).The overall procedure-related adverse events rate was 1.78% (95% CI, 0.62%-3.53%), and patients missed an average of 4.35 days (95% CI, 2.55-6.15 days) of work. In conclusion, laparoscopic radiofrequency ablation therapy is an efficacious way to treat small-sized and nonpedunculated symptomatic uterine fibroids, providing stable long-term symptom relief and quality of life improvement with a low risk of adverse events and reintervention

and just a few days of missed work. The authors identified several limitations. First, because most of the studies were non-comparative, differences in study types, inclusion and exclusion criteria, and study methodology were inevitable. Second, symptoms might be related to fibroid locations; however, not all studies classified patients by FIGO type, and so we could not analyze fibroids at different positions separately. In addition, the definition of procedure-related adverse events varied between studies, resulting in related data being based partially on the subjective judgment of the authors, not on objective definitions. Owing to the high loss to follow-up, the longest follow- up among the studies was 36 months. Therefore, long term follow-up data are still urgently needed.

In a systematic review and meta-analysis, Havryliuk et al. (2017) evaluated data from clinical studies that described populations of pre-menopausal women seeking surgical management (both uterine-sparing and hysterectomy) of their symptomatic fibroids. Procedures included in the analysis were myomectomy, UAE, Lap-RFA, MRg-FUS, and hysterectomy. Based on 209 patients (4 cohorts), the complication rate for Lap-RFA was overall 6.9% (1.7 major, 4.4% minor) with the reintervention rate 5.2%. Long-term follow-up averaged 27 months. The authors concluded that based on their analysis, Lap-RFA is associated with low complication rates, minimal EBL, and low reintervention rates. In addition, patients reported major improvement in their HRQL, and symptom severity scores compared to reports of more traditional interventions, such as hysterectomy, myomectomy, and UAE. Because of the precise placement of RF probe into a targeted myoma, which is confirmed by laparoscopic ultrasound before ablation, there is minimal disruption of normal myometrium and ovarian function. This is advantageous for patients who may desire future pregnancy. Pregnancy data are limited; however, normal full-term pregnancies resulting in vaginal deliveries have been reported after Lap-RFA. The authors state that limitations of this study include the inherent heterogeneity among studies; only a portion of the included studies were randomized controlled trials, most were not and were assigned an ACOG quality score of B; and lack of uniformity in reporting conventions. Further comprehensive prospective research, ideally in the form of well-powered randomized controlled trials, is needed to validate the specific treatment modality preferred for specific anatomical variances of fibroids.

Brucker et al. (2014, included in Hayes report and Bradley 2019 systematic review) conducted a randomized, single-center study comparing the perioperative outcomes of radiofrequency volumetric thermal ablation (RFVTA) and laparoscopic myomectomy (LM) in women who desired uterine conservation. Of 110 patients assessed for eligibility, 51 were randomized to the 2 interventions. The final analysis included 25 patients in the RFVTA group and 25 patients in the LM group. RFVTA resulted in the treatment of more fibroids, a significantly shorter hospital stay and less intraoperative blood loss than laparoscopic myomectomy. This study was sponsored by Halt Medical and is limited by small sample size and short-term follow-up.

At 12 months, Hahn et al. (2015, included in Hayes report and Bradley 2019 systematic review) reported similar clinical benefits in both groups. Mean symptom severity scores decreased (improved) by -7.8 for the ablation subjects and by -17.9 for the myomectomy subjects. Health-related quality of life improved (increased) by 7.5 and 13.1, respectively, for the two groups. Two myomectomy subjects had pregnancies that ended in a Cesarean delivery and a vaginal delivery of healthy infants. Two pregnancies in the RFVTA group ended in full-term vaginal deliveries of healthy infants.

At 24 months, Krämer et al. (2016, included in Hayes report and Bradley 2019 systematic review) reported improvements in the severity of symptoms from baseline by participants in both the RFVTA and LM groups. A significant improvement in health-related quality of life was observed in the LM group but not in the RFVTA group. A trocar-site hematoma occurred in one patient in the LM group. Further surgical interventions were recorded in three patients in the RFVTA group but these were unrelated to fibroid symptoms.

Galen et al. (2014, included in Bradley 2019 systematic review) performed a retrospective, multicenter clinical analysis of 206 consecutive cases of ultrasound-guided laparoscopic RFVTA of symptomatic uterine fibroids conducted under two phase II studies at 2 sites (n=69) and one phase III study at 11 sites (n=137). From baseline to 12 months in the phase II study, the mean transformed symptom severity scores improved from 53.9 to 8.8 (n=57), HRQOL scores improved from 48.5 to 92.0 (n=57) and mean uterine volume decreased from 204.4 cm3 to 151.4 cm3 (n=58). Patients missed a median of 4 days of work. The rate of possible device-related adverse events was 1.4%. In the phase III study, approximately 98% of patients were assessed at 12 months, and their transformed symptom severity scores, HRQOL scores, mean decrease in uterine volume and mean menstrual bleeding reduction were also significant. Patients in phase III missed a median of 5 days of work. The rate of periprocedural device-related adverse events was 3.5%. This study is limited by retrospective design, lack of randomization and control and short-term follow-up.

Chudnoff et al. (2013, included in Hayes report and Bradley 2019 systematic review) reported preliminary results of a prospective clinical trial designed to evaluate laparoscopic ultrasound-guided radiofrequency volumetric thermal ablation for treating symptomatic uterine fibroids. The study clinically supported by Halt Medical, Inc. included a cohort of 135 premenopausal symptomatic women with uterine fibroids and objectively confirmed heavy menstrual bleeding. Primary outcome measures were menstrual bleeding at 12 months compared to baseline (pre-procedure), adverse events and surgical reintervention rates. At 3-, 6- and 12-month follow-ups, menstrual blood loss decreased from baseline levels by 31.8%, 40.7% and 38.3%, respectively. Symptom severity decreased from baseline and health-related quality of life improved. The authors reported one serious adverse event requiring readmission 5 weeks postprocedure and one surgical reintervention for persistent bleeding. Ninety-four percent of the women reported satisfaction with the treatment. This study is limited by lack of randomization and control and short-term follow-up.

Berman et al. (2014, included in Bradley 2019 systematic review) reported 3-year outcomes of 104 patients from the Halt trial conducted by Chudnoff (2013). Questionnaire responses indicated sustained relief from symptoms and continued improvement in health-related quality of life through 36 months after ablation. The cumulative repeat intervention rate was 11% (14 of 135 participants) at 36 months. This study is supported by the study sponsor Halt Medical Inc., and limitations include lack of randomization and control.

In a systematic review prepared for AHRQ, Hartmann et al. (2017) found that the strength of evidence for radiofrequency ablation in the management of uterine fibroids is insufficient to inform care.

Transcervical Ultrasound-Guided Radiofrequency Ablation

In February 2019, Garza-Leal (included in Bradley 2019 systematic analysis) reported on the long-term (> 5 years) clinical outcomes of transcervical radiofrequency ablation of uterine fibroids. For this retrospective, single-arm, long-term data-collection study, 23 women with heavy menstrual bleeding secondary to fibroids were treated with transcervical radiofrequency ablation guided by integrated intrauterine sonography (using the Sonata® System, Gynesonics, Redwood City, CA). This study was within the 12-month Fibroid Ablation Study-EU clinical trial in Mexico. Symptoms were assessed using the Uterine Fibroid Symptom and Quality-of-Life's Symptom Severity Score (SSS) and Health-Related Quality of Life (HRQoL) subscales. Patients were queried regarding pregnancy and surgical reinterventions. The results showed seventeen women (73.9%) provided long-term follow-up information, with a mean of 64.4 months ±4.5 months. From baseline, mean SSS decreased significantly from 64.9 ± 16.9 to 27.6 ± 36.1, and mean HRQoL improved significantly from 27.2 ± 22.4 to 76.0 ± 32.6 respectively. There were no surgical reinterventions through the first 3.5 years post-treatment. There was an 11.8% incidence of surgical reinterventions over 5.4 years of average follow-up, with 2 hysterectomies occurring after 3.5 and 4 years postablation, respectively (event rate: 2.2% per year; 95% confidence interval; 0.3%, 7.9%). Freedom from surgical reintervention at 1, 2, and 3 years was 100%, and, at 4 and 5 years, was 88.2% ± 7.8%. There was a single pregnancy occurring within the first year of treatment leading to a normal-term delivery by elective repeat cesarean section. The authors concluded that transcervical radiofrequency ablation with the Sonata System produced substantial durable clinical benefits beyond 5 years with a low reintervention rate. This study is limited by a lack of randomization and small number of participants and the results should be validated in larger patient populations.

Chudnoff et al. (2019, included in Bradley 2019 systematic review) conducted a prospective, multicenter, single-arm interventional trial of patients treated in the United States and Mexico, to evaluate the 12-month safety and effectiveness of transcervical ablation for the treatment of symptomatic uterine leiomyomas. Transcervical ablation using the Sonata System was performed on 1-10 leiomyomas in 147 patients with leiomyoma diameters ranging from 1 to 5 cm. Treated leiomyomas included all nonpedunculated types. Primary endpoints assessed at 12 months were reduction in menstrual blood loss and absence of surgical reintervention. Additional assessments included symptom severity, quality of life, patient satisfaction, reductions in uterine and leiomyoma volumes, and safety. The study met its primary endpoints at 12 months ,because 64.8% of patients experienced 50% or greater reduction in menstrual bleeding and 99.3% of patients were free from surgical reintervention. The mean pictorial blood loss assessment chart score decreased by 38.9%, 48.4%, and 51.1% at 3, 6, and 12 months, respectively, and 95.1% of patients experienced a reduction in menstrual bleeding at 12 months. There were significant mean improvements in symptom severity and health-related quality of life of 32.1 points and 43.7 points, respectively, at 12 months. Mean maximal leiomyoma volume reduction per patient was 62.4%. More than half of patients returned to normal activity within 1 day, 96.3% of patients reported symptom improvement at 12 months, and 97% expressed satisfaction with the treatment at 12 months. There were no device-related adverse events. The authors concluded that transcervical ablation was associated with a significant reduction in leiomyoma symptoms with no device-related adverse events

and a low surgical reintervention rate through 12 months, demonstrating its potential to safely and effectively treat all nonpedunculated leiomyoma types through a uterus-conserving, incisionless approach.

Huirne and Brooks (2018) conducted a prospective, single-arm European trial in which 49 women with fibroids were treated with transcervical, intrauterine ultrasound- guided radiofrequency ablation with the Sonata System. The EQ-5D-3L system was utilized to collect patient health status at baseline, 3, 6, and, 12 months post-procedure. Patient-reported health states at each time point were converted into a health utility value using time-trade off methodology. Patient health utility increased from a mean of 0.745 at baseline, to means of 0.838, 0.852, and 0.914 at 3 months, 6 months, and 12 months, respectively. The change from baseline at 12 months was significant. Randomized controlled trials with larger patient populations and longer follow-up periods are needed to further evaluate the Sonata system.

Bongers et al. (2015, included in Bradley 2019 systematic review) conducted a prospective, longitudinal, multicenter, single-arm controlled trial to establish the effectiveness and confirm the safety of transcervical, intrauterine, ultrasound-guided radiofrequency ablation in the treatment of uterine fibroids. Fifty consecutive women with symptomatic uterine fibroids (n=92 fibroids) received treatment with the VizAblate System. The primary study endpoint was the percentage change in perfused fibroid volume at 3 months. Secondary endpoints, reached at 6 months, included safety, symptom reduction, rate of surgical reintervention and number of days to return to normal activity. Perfused fibroid volumes were reduced at 3 months by an average of 68.8 ± 27.8%. Six-month results suggest that the VizAblate System is safe and effective in providing relief of abnormal uterine bleeding associated with fibroids, with appropriate safety and a low reintervention rate. Similar results were reported at 12 months (Brölmann et al., 2016).

Garza-Leal et al. (2011) conducted a single center cohort study to evaluate the safety of the VizAblate transcervical device for the treatment of uterine fibroids. Nineteen women with uterine fibroids received treatment with the VizAblate System in a closed abdomen setting prior to hysterectomy. Twelve women underwent an immediate abdominal hysterectomy after radiofrequency ablation (acute group), while the remaining seven underwent hysterectomy on post-ablation days 16 and 17 (subacute group). Uteri were analyzed to quantify fibroid ablation dimensions and assess the serosa for thermal injury. Subjects in the subacute group were treated under conscious sedation and indicated overall procedural satisfaction. There were no complications or thermal serosal injury. For women in the subacute group receiving one ablation, the mean total procedure time was 25.8 ± 6.0 minutes (range 18–32 minutes). All subjects in the subacute group were discharged within 2 hours of the procedure. For fibroids ≤ 5 cm, 67.2% ± 27.0% of the fibroid volume was ablated (range 15–100%; median 75%). The authors concluded that transcervical radiofrequency ablation of fibroids under intrauterine sonographic guidance with the VizAblate system can be accomplished with a high degree of reliability and without adverse events.

Toub (2017) evaluated the clinical evidence for the Sonata System, the results of which showed significant median reductions in total (73.3%) and perfused (73.3%) uterine fibroid volume, menstrual bleeding (72.3%), symptom severity (62.5%), and improvements in health-related quality of life (127%) at 12 months post-ablation. In the author's opinion, the Sonata System is a promising treatment modality for uterine fibroids that does not require general anesthesia or hospitalization, and has the potential for redefining the current paradigm for management of symptomatic fibroids. Randomized controlled trials with longer follow-up periods are needed to evaluate the safety and reliability of this procedure.

Professional Societies

American College of Obstetricians and Gynecologists (ACOG)

An ACOG committee opinion on acute abnormal uterine bleeding concludes that surgical management should be considered for patients 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. The report also mentions the use of levonorgestrel-releasing IUDs as an option for the long-term treatment of chronic AUB (ACOG, 2013; reaffirmed 2017).

Levonorgestrel-Releasing Intrauterine Device

An ACOG practice bulletin on the use of noncontraceptive uses of hormonal contraceptives states 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 2016). (Evidence Level B – Based on limited or inconsistent scientific evidence.)

In a practice bulletin on alternatives to hysterectomy in managing uterine fibroids, ACOG states that the levonorgestrel intrauterine system leads to minimal systemic effects, and the localized endometrial effect is beneficial for treatment of menorrhagia. Small studies suggest that the levonorgestrel intrauterine system may be effective for treatment of heavy uterine bleeding in women with leiomyomas. However, these women may have a higher rate of expulsion and vaginal spotting (ACOG, 2008; reaffirmed 2016).

Magnetic Resonance Imaging-Guided Focused Ultrasound Ablation

In a practice bulletin on alternatives to hysterectomy in managing uterine fibroids, ACOG states that while short-term studies show safety and efficacy, long-term studies are needed to discern whether the minimally invasive advantage of MRgFUS will lead to durable results beyond 24 months (ACOG, 2008; reaffirmed 2016).

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 MRg-FUS (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 Radiology (ACR)

ACR appropriateness criteria conclude the following:

- Uterine artery embolization (UAE) is effective in managing symptomatic uterine fibroids.
- UAE and myomectomy have similar clinical success and complication rates.
- There is little long-term information on the efficacy of MRgFUS.
- A full gynecologic workup, including a Pap smear every 3 years and/or an endometrial biopsy if a patient has menometrorrhagia before UAE is performed (ACR, 2018).

American Academy of Family Physicians

An endometrial biopsy is an office procedure that serves as a helpful tool in diagnosing various uterine abnormalities. Endometrial biopsy is a safe and accepted method for the evaluation of abnormal or postmenopausal bleeding. The procedure is often performed to exclude the presence of endometrial cancer or its precursors such abnormal uterine bleeding (Zuber 2001).

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 heavy menstrual bleeding 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 6, 2019)

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 2, 2020)

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 2, 2020)

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 2, 2020)

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. See the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P040003S009 (Accessed July 2, 2020)

Laparoscopic Ultrasound-Guided Radiofrequency Ablation

The Acessa System received FDA clearance for marketing on November 5, 2012 (K121858). The device is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. See the following website for additional information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K132744. (Accessed July 2, 2020)

The Acessa ProVu System, the next generation of the Acessa System, received FDA clearance on September 28, 2018. It is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. See the following website for additional information: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181124.pdf. (Accessed July 2, 2020)

The Sonata® Sonography-Guided Transcervical Fibroid Ablation System received FDA clearance for marketing on August 15, 2018. This device is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding. See the following website for additional information: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173703.pdf. (Accessed July 2, 2020)

Laparoscopic Power Morcellation Warning

A February 25, 2020 FDA Safety Communication recommends performing laparoscopic power morcellation for myomectomy or hysterectomy only with a tissue containment system (legally marketed in the U.S.) for use during laparoscopic power morcellation and performing only in appropriately selected patients.

See the following website for additional information: https://www.fda.gov/medical-devices/safety-communications/update-fda-recommends-performing-contained-morcellation-women-when-laparoscopic-power-morcellation. (Accessed July 16, 2020)

A November 24, 2014 FDA Safety Communication 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 long-term survival of patients. This information should be shared with patients 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 patients 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.

See the following website for additional information:
http://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM424444.pdf. (Accessed July 16, 2020)

In December 2017, the FDA released new findings on the risks of spreading hidden uterine cancer through the use of laparoscopic power morcellators which suggests that approximately 1 in 225 to 1 in 580 women who undergo surgery (hysterectomy or myomectomy) for presumed benign uterine growths may have occult or hidden uterine cancers known as sarcomas. This is generally consistent with the 1 in 350 incidences estimated by the FDA in a 2014 review. The FDA also estimates the rate of occult leiomyosarcoma, a particularly aggressive type of sarcoma, to be approximately 1 in 495 to 1 in 1100, again in general agreement with our previous assessment of 1 in 498. Ranges in incidence represent estimates based on differing statistical analyses of available study data.

A white paper published in December 2017 provides an update on medical device reports the FDA received through April 2017 related to the use of laparoscopic power morcellators and how hysterectomy and myomectomy procedure selection has changed since the FDA's 2014 warning against the routine use of morcellators to treat suspected uterine fibroids. This data demonstrates that overall, use of laparoscopic power morcellators has decreased since the FDA warned about it in 2014.

See the following website for additional information:
https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/UCM584539.pdf. (Accessed July 16, 2020)

Transcervical Ultrasound-Guided Radiofrequency Ablation

The Sonata® Sonography-Guided Transcervical Fibroid Ablation System received FDA 510(k) marketing clearance on August 15, 2018. It is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding. See the following website for additional information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K173703. (Accessed July 16, 2020)

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Policy History/Revision Information

Date	Summary of Changes
07/01/2021	Coverage Rationale • Replaced reference to "InterQual® 2020" with "InterQual® 2021" Supporting Information • Archived previous policy version CS002IN.01

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, please 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.

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