



Medical Coverage Policy

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Ultrasound-guided Radiofrequency Ablation for Uterine Fibroids

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Related Coverage Resources

[High Intensity Focused Ultrasound \(HIFU\)](#)

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Overview

This Coverage Policy addresses the use of ultrasound-guided radiofrequency ablation for the treatment of symptomatic uterine fibroids.

Coverage Policy

Ultrasound guided radiofrequency ablation is considered medically necessary for the treatment of symptomatic uterine fibroids.

General Background

Uterine fibroids (UF), also referred to as leiomyomas or myomas, are benign noncancerous tumors of the myometrium, the smooth muscle layer of the uterus. They are the most common pelvic tumor that arise in reproductive-age women (Stewart and Laughlin-Tommaso, 2021). Approximately 25% of fibroids cause symptoms of abnormal uterine bleeding and/or pelvic pain/pressure and are the most common indication for

hysterectomy. It is estimated that approximately 26 million women in the US have uterine fibroids with Black women experiencing UF up to three times more frequently, at a younger age and with larger and more numerous tumors than other racial groups (Stewart and Laughlin-Tommaso, 2021; Hartmann, et al., 2017; Laughlin et al., 2009; Wise et al., 2005; Baird, et al., 2003). Risk factors for developing fibroids include race; reproductive and endocrine factors such as parity, early menarche, hormonal contraception; obesity; diet, alcohol and smoking; and genetics.

Symptoms related to uterine fibroids are classified into the following categories:

- Heavy or prolonged menstrual bleeding
- Bulk-related symptoms, such as pelvic pressure
- Reproductive dysfunction (i.e., infertility or obstetric complications)
- Pain

The location of the fibroid is important in determining the presence and degree of uterine bleeding with size being of secondary importance. The FIGO (the International Federation of Gynecology & Obstetrics) classification system is used to describe the location of fibroids within the uterus: type 0–2 fibroids have submucous involvement, type 3 fibroids abut the endometrium but are completely intramural, type 4 fibroids are completely intramural, types 5 and 6 fibroids have serosal involvement, type 7 fibroids are pedunculated on the subserosal surface, and type 8 fibroids are identified in ectopic locations (Munro, et al., 2011). Significant heavy menstrual bleeding occurs in submucosal myomas that protrude into the uterine cavity, intramural myomas, and cervical fibroids that are close to the endocervical canal. Subserosal fibroids are not associated with heavy menstrual bleeding. Bulk-related symptoms occur due to the enlargement and irregular shape of the uterus. These symptoms include pelvic pain or pressure, urinary tract or bowel obstruction, or venous compression. If discomfort is present, it is likely to be chronic, intermittent, dull pressure or pain. Depending on their size and location, the urinary tract or bowel may be compressed by fibroids. A very large uteri can compress the vena cava leading to an increase risk for thromboembolism. Other pain and discomfort issues include painful menses, intercourse and with fibroid degeneration or torsion. The distortion of the uterine cavity caused by fibroids has been thought to contribute to difficulty in conceiving a pregnancy or infertility. Leiomyomas have been associated with adverse pregnancy outcomes including placental abruption, fetal growth restriction, malpresentation, and preterm labor and birth (Stewart and Laughlin-Tommaso, 2021).

Treatment options for symptomatic UF include medication, hysterectomy, myomectomy, hysteroscopic resection and ablation, uterine artery embolization (UAE), and radiofrequency ablation (RFA). Magnetic resonance imaging–guided ultrasound surgery (MRgFUS) has been proposed as a non-invasive technique used to ablate uterine fibroids in women who do not intend to become pregnant in the future. The choice of treatment is guided by the type of symptoms in the individual patient and whether they prefer to retain fertility. Hysterectomy provides definitive resolution of fibroid symptoms, however this procedure is invasive with long recovery times. Many patients desire a less invasive, uterus preserving approach. Myomectomy is a surgical procedure to remove uterine fibroids while leaving the uterus intact. It can be done using an abdominal, laparoscopic, hysteroscopic, or vaginal approach. Complications from abdominal myomectomy includes hemorrhage, conversion to hysterectomy, fever and infection, and adhesive disease (Parker, 2020). Hysteroscopic complications include uterine perforation, urinary tract or bowel injury, cervical laceration, excessive fluid absorption, embolism, hemorrhage, electrosurgical injury or infection (Bradley, 2020). Uterine artery embolization (UAE) is a minimally invasive and uterus sparing option. UAE is a percutaneous angiographic procedure performed with video fluoroscopic imaging and performed by a trained interventional radiologist. Common complications are self-limited and include pelvic pain, fever, and vaginal discharge. Serious complications are the introduction of embolic agents into inadvertent vessels, necrosis of the gluteus maximus or limb, or pulmonary embolism (van der Kooij and Hehenkamp, 2020). Magnetic resonance imaging–guided ultrasound surgery (MRgFUS) utilizes high intensity ultrasound energy to induce coagulative necrosis of fibroids. It is a noninvasive, outpatient procedure that targets each fibroid individually. Reported adverse effects of MRgFUS have included paresthesia, burns on the abdomen, excessive postoperative bleeding, and reactions to medication.

Laparoscopic Radiofrequency Ablation (RFA) of Uterine Fibroids (CPT code 58674)

Laparoscopic RFA has been proposed for the treatment of uterine fibroids (UF). In this minimally invasive procedure, a laparoscopic ultrasound probe is used to determine the location and size of fibroids. An electrode

array delivers alternating radiofrequency energy to drive a current through the tissue to be ablated, causing controlled, local heating, resulting in targeted tissue destruction.

U.S. Food and Drug Administration (FDA): The Acesa System (Halt Medical, Inc., Brentwood, CA) was given 510(k) approval in November 2012. According to the approval summary this system is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. The FDA specifically notes the Acesa System must be used under laparoscopic ultrasound guidance. Laparoscopic ultrasound equipment is not included with the Acesa System.

In October 2018, the next generation of the Acesa System, received 510(k) FDA approval for the Acesa ProVu System. It is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. The Acesa ProVu System includes optional electromagnetic guidance for enhancing the ultrasonic image of the Acesa ProVu Handpiece and for predicting its future path on a computer monitor screen which also shows the ultrasound B-scan image.

Literature Review

Peer-reviewed published clinical trial data include two randomized controlled trials (Brucker, 2014; Hahn, et al., 2015; Kramer, et al., 2016; Rattray, et al., 2018) and several nonrandomized, uncontrolled prospective studies, also with small participant numbers. Chudnoff et al. (2013), Guido et al. (2013) and Berman et al. (2014) reported 12-, 24- and 36-month follow-up of the same nonrandomized prospective interventional trial involving 135 women with symptomatic uterine fibroids. The comparator evaluated in the eligible studies was laparoscopic myomectomy (LM) in two studies (Brucker, et al., 2014; Hahn, et al., 2015; Kramer, et al., 2016; Rattray, et al., 2018). The studies are generally limited by uncontrolled, nonrandomized study design, small size and lack of comparison to other treatment methods.

Hayes evaluated the safety and efficacy the Acesa System for treatment of uterine fibroids (Hayes, 2014; 2019). The review included six clinical studies reported in 11 publications that evaluated the efficacy and safety of radiofrequency volumetric thermal ablation (RFVTA) with the Acesa System for treatment of symptomatic UF. The only comparator evaluated in the eligible studies was laparoscopic myomectomy (LM) (in two studies). Follow-up periods ranged from three months to three years.

The review noted regarding effectiveness:

- Symptom severity (six studies): Evidence suggests that RFVTA generally resulted in statistically significant improvements from baseline in symptomatology. RFVTA did not result in any statistically significant differences in UF-related symptom severity or quality of life (QOL) compared with LM; however, comparative analyses were limited to two studies and were not always conducted statistically.
- General QOL (four studies): Comparatively, one study performed a between-group analysis at 12 months and found no statistically significant differences between scores of the SF-36 Health Survey (SF-36) (RAND Corp.) among patients who received RFVTA or LM. Other evaluations demonstrated statistically significant improvements from baseline at three months (one study) and 36 months (one study). A third study found changes from baseline were statistically significant on the mental component of the SF-36 at six weeks but not 12 weeks; changes from baseline were statistically significantly improved on the physical component at both six and 12 weeks.
- Recovery (six studies): Time to return to normal activity ranged from 3.4 to 20.5 days for those treated with RFVTA. Differences were not assessed statistically in the only comparison of RFVTA and LM at the 3-month follow-up. Missed work varied among studies, ranging from 4.1 to 11 days. Compared with LM, treatment with RFVTA resulted in statistically significantly less days missed from work at three months according to one study (11.1 versus 18.5; $P=0.0193$). A second comparative study did not assess statistical differences between RFVTA (10 days) and myomectomy (17 days).
- Uterine volume (three studies): Reductions in mean uterine volume were statistically significant in two studies, ranging from 24.3% to 41.8% at 12 months follow-up ($P<0.05$). Of these studies, one study also noted significant uterine reduction at three months (15.7%; $P<0.001$). A third study evaluated uterine volume reduction at 12 months and found no statistically significant difference from baseline (21% change from baseline; $P=0.192$).

- Fertility and pregnancy outcomes (two studies): No studies evaluated success in achieving pregnancy among women attempting to conceive after RFVTA. Two studies reported pregnancies among patients who underwent RFVTA compared with LM. One RCT reported that no pregnancies had occurred as of three months follow-up. A second RCT reported three pregnancies in patients undergoing RFVTA and six pregnancies in patients undergoing LM; however, no analysis was performed regarding the proportion of patients who achieved pregnancy out of the proportion of patients who were attempting to conceive.

Regarding safety: Patients reporting any adverse event ranged from 4% to 32%. Adverse events reported in the eligible studies were uncommon and included hypermenorrhea, uterine cramping, nausea, vomiting, migraine, hematoma at trocar site, vertigo, abdominal pain, urinary tract infection, abdominal wall injury, pelvic abscess, laceration of sigmoid colon, vaginal bleeding, severe lower abdominal pain, uterine serosal burn, abnormal vaginal discharge, skin infection, bloating, constipation, intestinal inflammation, flu-like symptoms, sinus infection, sore gums, swollen throat glands, upper respiratory infection, skin blisters, arthritis, and skin irritation. In the eligible studies, one patient experienced severe bleeding during a cesarean section and early postpartum period which was deemed as possibly related to treatment with RFVTA.

Regarding quality of evidence: The overall low-quality body of evidence was due to individual study quality, lack of evidence comparing RFVTA with other minimally invasive techniques, and lack of evaluation of the safety of RFVTA in women who wish to maintain fertility and achieve pregnancy. Of the eligible studies, one was of fair quality, four were of poor quality, and one was of very poor quality. Additional limitations noted in the studies included lack of randomization, lack of active comparators, small sample sizes, lack of power analyses, high attrition rates, censored data for patients lost to follow-up, limited follow-up, and limited statistical analyses.

The review noted that large, well-controlled trials comparing RFVTA with other minimally invasive, uterine-sparing procedures are needed especially evaluating the safety and effectiveness of RFVTA among women wishing to maintain fertility.

Systematic Review and Meta-Analysis

Lin et al. (2019) conducted a meta-analysis to assess the short-term (three and six 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. Both comparative and non-comparative studies consisting of uterine fibroid symptoms and quality of life scores were included. Eight studies (one RCT, seven non-comparative) with a total of 581 patients were included in the 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 cm³ (95% CI, 35.87-102.46 cm³). 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. Limitations of the studies include that most of the studies were noncomparative studies. The author notes that there were differences in study types, inclusion and exclusion criteria, and study methodology.

Bradley et al. (2019) conducted a systematic review of prospective studies for treatment of uterine fibroids with radiofrequency ablation (RFA). Main outcomes were procedure time, patient recovery metrics, change in fibroid volume, symptom severity score (SSS), health-related quality of life (HRQL), and reinterventions. Data were analyzed with random effects meta-analysis and metaregression. The review included 32 articles of 1283 unique patients treated with laparoscopic RFA (19 articles), transvaginal RFA (8 articles), or transcervical fibroid ablation (5 articles) and included randomized trials, comparative cohort studies, and noncomparative cohort studies. Mean procedure time was 49 minutes, time to discharge was 8.2 hours, time to normal activities was 5.2 days, and time to return to work was 5.1 days. At 12 months follow-up, fibroid volume decreased by 66%, HRQL increased by 39 points, and SSS decreased by 42 points (all P < .001 versus baseline). The annual cumulative rate of reinterventions due to fibroid-related symptoms was 4.2%, 8.2%, and 11.5% through 3 years. The study did not specify results according to the treatment method.

Sandberg et al. (2018) conducted a systematic review and meta-analysis to compare uterine-sparing treatment options for fibroids in terms of reintervention risk and quality of life. The review included randomized controlled trials (RCT) and cohort studies (both noncomparative and comparative). The main outcome measures included: reintervention risk after uterine-sparing treatment for fibroids after 12, 36, and 60 months; and quality of life outcomes, based on validated questionnaires. Two separate analyses were performed for the procedures that used an abdominal approach (myomectomy, uterine artery embolization [UAE], artery ligation, high-intensity focused ultrasound [HIFU], laparoscopic radiofrequency ablation [RFA]) and for the procedures managing intracavitary fibroids (hysteroscopic approach, including hysteroscopic myomectomy and hysteroscopic RFA). The review included 85 articles for analysis (17,789 women). Stratified by treatment options, reintervention risk after 60 months was 12.2% (95% confidence interval [CI] 5.2%-21.2%) for myomectomy, 14.4% (95% CI 9.8%-19.6%) for UAE, 53.9% (95% CI 47.2%-60.4%) for HIFU, and 7% (95% CI 4.8%-9.5%) for hysteroscopy. For the other treatment options, no studies were available at 60 months. For quality of life outcomes, symptoms improved after treatment for all options. Laparoscopic RFA included eight studies, with 652 patients.

Havryliuk et al. (2017) reported on a systematic review and meta-analysis for the purpose of determining whether recommendations can be made regarding best practice based on review and analysis of the literature that addressed clinical outcomes associated with interventions for the management of symptomatic uterine fibroids. Outcomes of interest were patient baseline characteristics, fibroid characteristics, procedural details, complications, and long-term follow-up. The review included hysterectomy trials compared with those from uterine-preserving fibroid studies (myomectomy, uterine artery embolization (UAE), laparoscopic radiofrequency ablation (lap-RFA), and magnetic resonance-guided focused ultrasound). For lap-RFA, the long-term follow-up averaged 27 months in four cohorts with 209 patients. For lap-RFA the analysis in the review indicated that Lap-RFA is associated with low complication rates, minimal estimated blood loss, and low reintervention rates. In addition, patients reported major improvement in their Health-Related Quality of Life (HRQL) and symptom severity scores compared to reports of more traditional interventions, such as hysterectomy, myomectomy, and UAE. The authors note that the study is limited by the inherent heterogeneity among studies and that although some of the included studies were randomized controlled trials, most were not. The review concluded that currently available data regarding certain fibroid characteristics, such as size, location, or number are insufficient to assign specific cutoffs that favor one treatment modality over another and recommended further comprehensive prospective research, ideally in the form of well-powered randomized controlled trials, to validate the specific treatment modality preferred for specific anatomical variances of fibroids.

Taheri et al. (2019) conducted a systematic review to examine 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 included: 52 related to UAE, 11 to RFA, 17 to FUS, and one compared UAE and FUS. The report noted the published uterine volume and fibroid volume changes in the studies at one 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 with fibroid volume reduction most marked with RFA; with UAE resulting in the next most volume reduction. The authors note that additional larger cohort studies, including those that are randomized and/or comparative, would enable definitive conclusions.

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

Studies

Ratray et al (2018) conducted a study to compare laparoscopic ultrasound-guided radiofrequency ablation of fibroids (Lap-RFA) and laparoscopic myomectomy in terms of health care utilization and serious complication rates. Secondary objectives were comparison of subject responses to validated symptom and quality-of-life questionnaires. The randomized, prospective, multicenter, longitudinal, non-inferiority interventional comparative evaluation included 45 participants (Lap-RFA n=23; myomectomy n=22) who were premenopausal with symptomatic uterine fibroids and desired uterine conservation. Health care resource utilization was measured during the procedure day and at one week, one and three months post-surgery. Symptom severity and quality of life were based on patients' responses to the Uterine Fibroid Symptom Severity and Quality-of-Life Questionnaire, EuroQoL-5D-visual analog scale general health status and menstrual impact questionnaires, and

time from work. Hospitalization time (primary endpoint) was 6.7 ± 3.0 hours for the Lap-RFA group and 9.9 ± 10.7 hours for the myomectomy group ($p=0.0004$). Intraoperative blood loss was lesser for Lap-RFA subjects: 25.2 ± 21.6 versus 82.4 ± 62.5 mL ($p=0.0002$). Lap-RFA procedures took less time than myomectomy procedures: 70.0 versus 86.5 minutes ($p=0.018$), and Lap-RFA required -34.9% (130 fewer) units of surgical equipment. At three months, both cohorts reported the same significant symptom severity reduction (-44.8%; $p<0.0001$). Lap-RFA subjects also took less time from work: 11.1 ± 7.6 versus 18.5 ± 10.6 days ($p=0.0193$). One myomectomy subject was hospitalized overnight after experiencing a 20-second asystole during the procedure. One Lap-RFA subject underwent a reintervention. Limitations include the small number of participants. The authors noted that the lack of long-term data was a limitation; the data was based on outcomes to three months post-intervention and, therefore, the durability of the symptom improvement and pregnancy outcomes could not be evaluated for either procedure.

Brucker et al. (2014) reported outcomes of a randomized, prospective single-center international clinical trial involving 51 women comparing radiofrequency volumetric thermal ablation (RFVTA) ($n=26$) and laparoscopic myomectomy (LM) ($n=25$) for symptomatic uterine fibroids. Primary outcomes were the mean hospital discharge times and perioperative outcomes. The predominant symptom reported by the patients in both groups was heavy menstrual bleeding followed by urinary frequency, pelvic discomfort and pain, backache, localized pain, dysmenorrhea, urinary retention, increased abdominal girth, dyspareunia, uterine pain, and sleep disturbance. There were no significant differences based on Fisher exact test between the two groups with regard to any of these symptoms, although the authors note this could be because of the relatively small number of patients in each group. Surgeons were blinded to the treatment until all fibroids were mapped by laparoscopic ultrasound. The mean hospitalization times were 10.0 ± 5.5 hours for the RFVTA group and 29.9 ± 14.2 hours for the LM group ($p=.16$). Intraoperative blood loss was 16 mL for the RFVTA procedures and 51 mL for the LM procedures. The percentage of fibroids imaged by laparoscopic ultrasound that were treated/excised was 98.6% for RFVTA and 80.3% for LM. Two complications were reported: vertigo ($n=1$; RFVTA) and port site hematoma ($n=1$; LM). The mean time between arrival in post-anesthesia recovery and discharge from the hospital was 8.2 hours for the RFVTA group and 28.0 hours for the LM group ($p<0.001$). Mean hospitalization time was 10.0 hours and 29.9 hours for the RFVTA and LM groups, respectively, $p<0.001$. The authors note that short-term follow-up is a limitation to the study and plan five-year follow-up for pregnancy outcomes, symptom improvement, and overall treatment satisfaction as evaluated on the basis of participants' responses to validated questionnaires. The study is limited by small study participant numbers.

Hahn et al. (2015) published one year results of the above study (Brucker, et al., 2014) with objective to analyze, compare and describe the study's three, six and twelve month outcomes in terms of pain medication use, recovery from surgery, and subjects' subjective responses to validated questionnaires. The results included: post-surgery, ablation and myomectomy subjects took pain medications for 4 days (range: 1–46) and 7 days (range: 1–83 days) respectively ($p=0.60$); ablation and myomectomy patients missed 10.0 workdays (range: 2–86 days) and 17.0 workdays (range: 7–30 days) ($p=0.28$); resumed normal activities in 20.5 days (range: 5–103 days) versus 28.0 days (range: 10–42 days) ($p=0.86$) respectively. The mean symptom severity scores decreased (improved) by -7.8 for the ablation subjects and by -17.9 for the myomectomy subjects ($p=0.16$). Health-related quality of life improved (increased) by 7.5 and 13.1, respectively, for the two groups ($p=0.46$). 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. The authors concluded that early postoperative recovery and twelve-month results indicate similar efficacy, quality of life, and safety for both treatment groups. The subjects will be continued to be followed for five years.

Kramer et al. (2016) reported on 24 month data from the above study (Brucker, et al., 2014). The outcomes included this analysis were patients' responses to validated questionnaires and long-term safety. The study included 51 patients with 21 and 22 patients in the RFVTA and laparoscopic myomectomy groups, respectively that completed 24 months of follow-up. There was improvement reported in the severity of symptoms from baseline by participants in both the RFVTA ($P<0.001$) and laparoscopic myomectomy groups ($P=0.001$). The study observed a significant improvement in health-related quality of life in the laparoscopic myomectomy group ($P=0.040$); and a non-significant improvement was noted in the RFVTA group ($P=0.083$). A trocar-site hematoma occurred in one patient in the laparoscopic myomectomy group. There were further surgical interventions recorded in three patients in the RFVTA group but it was noted that these were unrelated to fibroid symptoms.

Jacoby et al. (2019) conducted a single-arm, unblinded, uncontrolled trial to assess surgical outcomes, clinical effectiveness, and gynecologist experience of introducing laparoscopic radiofrequency ablation (RFA) of leiomyomas into surgical practice. The study included 26 women who were premenopausal with symptomatic uterine leiomyomas, uterus size ≤ 16 weeks size, and all leiomyomas ≤ 10 cm with no more than 6 total leiomyomas and who underwent the RFA treatment. Intraoperative complications, blood loss, operative time, and adverse events were assessed. Gynecologists reported the operative difficulty and need for further training after each case. Participants reported leiomyoma symptoms preoperatively and at 6 and 12 weeks after surgery. The mean operating time was 153 ± 51 minutes, and mean estimated blood loss was 24 ± 40 cc. There were no intraoperative complications and no major adverse events. Menstrual bleeding, sexual function, and quality of life symptoms improved significantly from baseline to 12 weeks, with a 25 ± 18 -point, or 47%, decrease in the Leiomyoma Symptom Severity Score. The study was limited by the low number of participants.

Berman et al. (2019) conducted a case series to analyze pregnancy delivery and safety outcomes after patient receipt of percutaneous, laparoscopic intra-abdominal ultrasound-guided radiofrequency ablation (Lap-RFA) for symptomatic uterine myomas. Evidence was obtained from two randomized, controlled trials (level I), six cohort studies (level II-2), and in commercial settings (level II-3). The study included premenopausal adult women with symptomatic uterine myoma types 1 through 6 with Lap-RFA procedure conducted under general anesthesia with laparoscopic and intra-abdominal ultrasound guidance. Safety unknowns included the safety of a full-term pregnancy for mother and baby, rates of spontaneous abortion, preterm delivery, postpartum hemorrhage, placental abnormalities, intrauterine growth restriction, and vaginal versus cesarean delivery. A total of 28 women conceived a total of 30 times after Lap-RFA, either as part of a clinical study or in commercial settings. The number of myomas treated per patient ranged from one to seven. The diameter of treated myomas ranged from 0.9 to 11.0 cm. Most patients had one or two myomas, and most myomas were ≤ 5.5 cm in maximal diameter. The 30 pregnancies resulted in 26 full-term live births (86.7%), all healthy infants, with an equal distribution of vaginal and cesarean deliveries. Four (13.3%) spontaneous abortions occurred. No cases of preterm delivery, uterine rupture, placental abruption, placenta accreta, or intrauterine growth restriction were reported. One event each of placenta previa and postpartum hemorrhage were reported. The authors concluded that conception and safe, full-term pregnancy appear to be achievable after Lap-RFA of symptomatic myomas, however, additional large, rigorous, multivariate prospective studies that adjust for confounders and report pregnancy outcomes after symptomatic myoma treatment are needed.

Chudnoff et al. (2013) reported one year results of a prospective, multicenter, interventional clinical trial (i.e., HALT trial) with primary outcome measures of change from baseline to 12 months and ongoing qualitative follow-up of women for three years in a cohort of 135 premenopausal symptomatic women with uterine myomas, uteri 14 weeks of gestation-sized or less with no single myoma exceeding 7 cm, and objectively confirmed heavy menstrual bleeding. Primary intervention was outpatient laparoscopic ultrasound-guided radiofrequency volumetric thermal ablation using the Acessa system (Halt Medical, Brentwood, CA). Bleeding outcomes and validated quality-of-life and patient satisfaction scales and objective measurements of uterine and myoma volume were conducted at 3, 6, and 12 months. Mean alkaline hematin and associated menstrual blood loss decreased from baseline levels by 31.8%, 40.7%, and 38.3%, respectively, at three-, six-, and 12-month intervals ($p < .001$ for all). Symptom severity and health-related quality of life improved ($p < .001$). There was one serious adverse event (0.7%) requiring readmission 5 weeks post-procedure and one surgical reintervention for persistent bleeding. Ninety-four percent of the women reported satisfaction with the treatment ($p < .001$). The study was limited by uncontrolled design, short-term follow-up and a lack of comparison to other treatment methods.

In a follow-up to the study by Chudnoff et al. (2013), Guido et al. (2013) reported two-year outcomes of 124 subjects who participated in the HALT trial, of whom 112 were evaluable. Outcome measures included: subject responses to validated questionnaires, treatment-emergent adverse events, and surgical reintervention for fibroids at 24 months post-procedure. Significant changes from baseline were noted in symptom severity ($p < .001$) and health-related quality of life scores ($p < .001$). There was a significant improvement in the mean health state score between baseline and 3 months after treatment ($p < .001$). Measurements at subsequent intervals showed no continued improvement. Six patients underwent surgical reintervention for fibroid-related bleeding between 12 and 24 months. The authors also reported on one patient who had an episode of bleeding post Cesarean section requiring receipt of six units of blood, which the study authors noted as possibly related to the

RFA procedure. Limitations to the study include uncontrolled design, lack of comparator, short-term follow-up and small total patient numbers.

In a thirty-six month follow-up study, Berman et al. (2014) reported subject responses to validated questionnaires and surgical repeat intervention to treat myomas outcomes for a cohort of 104 evaluable patients (104/135) who participated in the HALT trial. Change in mean symptom severity ($p < .001$) and Health-Related Quality of Life questionnaire scores ($p < .001$) were improved from the baseline. Patient-reported Uterine Fibroid Symptom and Health-Related Quality of Life questionnaire subscores demonstrated statistically significant improvement from baseline to 36 months ($p < .001$) in all categories (i.e., Concern, Activities, Energy/Mood, Control, Self-consciousness, and Sexual Function). The cumulative repeat intervention rate was of 11% at 36 months. Although results are promising, study limitations include uncontrolled, nonrandomized design, lack of comparison to other treatment methods, and small study participant numbers.

Robles et al. (2013) assessed outcomes of a prospective study assessing the laparoscopic radiofrequency volumetric thermal ablation (RFVTA) system among 114 screened women with symptomatic myomas. Thirty-five women completed the 12-month follow-up period. Uterine fibroid symptom and health-related quality-of-life (UFS-QOL) questionnaires were completed at zero, three-, six-, and 12-months. There was a significant reduction in average symptom severity score over the study period ($p < 0.001$), and reductions in symptom severity scores from baseline to each of the follow-up visits, and from the 3-month visit to the 12-month follow-up visit were significant ($p < 0.001$). There was a significant increase in average health-related quality of life (HRQL) scores from baseline to 12 months ($p < 0.001$) and in the HRQL scores from baseline to each of the follow-up visits ($p < 0.001$). After discharge, none of the participants was admitted to hospital for procedure-related complications. Within the study period, none of the participants required hysterectomy or any myoma treatment after RFVTA. No transfusions were required. Nine adverse events among eight women were reported as definitely not device- or procedure-related. Study limitations which limit the ability to routine clinical practice include lack of randomization and control, small study population, short-term follow-up of 12 months and lack of comparison to other treatment methods.

Thirty-one women with symptomatic uterine fibroids underwent outpatient laparoscopic, ultrasound-guided, radiofrequency volumetric thermal ablation using the Halt 2000 System. Postoperative follow-up occurred at three, six, and 12 months. The primary outcome measures were patient safety, frequency of adverse events, repeat intervention rate, symptom severity and health-related quality-of-life scores from the validated Uterine Fibroid Symptom and Quality-of-Life Questionnaire. Secondary outcome measures were uterine volume changes over time. Mean symptom severity scores improved significantly compared with baseline at three, six, and 12 months. Mean health-related quality-of-life scores reached statistical significance over time. Mean uterine volume decreased at three six, and 12 months. There were no procedure-related repeat hospitalizations, repeat treatments or procedures related to fibroid symptoms following treatment. The study is limited by lack of randomization and control, short-term follow-up, small sample size and lack of comparison to other treatment methods. Larger multicenter studies are needed to confirm these results (Garza, 2011).

Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency (CPT code 0404T)

Radiofrequency transcervical uterine fibroid ablation with ultrasound guidance has been proposed for the treatment of uterine fibroids. The Sonata® Sonography-Guided Transcervical Fibroid Ablation System (Gynesonics; Redwood City, CA), has been developed to provide transcervical radiofrequency ablation (RFA) for treatment of uterine fibroids. The Sonata System combines a miniaturized, reusable, intrauterine ultrasound probe and a single-use RFA handpiece that contains an introducer and needle electrode array; the device is introduced into the uterus via a transcervical approach and the ablation is initiated by foot control. The Sonata System is designed to treat patients in an outpatient setting, depending on anesthetic requirements (general anesthesia, conscious sedation, or spinal anesthesia) (Hayes, 2018). The Sonata system was previously known as the VizAblate System.

U.S. Food and Drug Administration (FDA):

The FDA granted a 510(k) marketing clearance for the Sonata Sonography-Guided Transcervical Fibroid Ablation System in August 2018. The Sonata Sonography-Guided Transcervical Fibroid Ablation System is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.

Literature Review

Chudnoff et al. (2019) reported on a prospective, multicenter, single-arm interventional trial to evaluate the 12-month safety and effectiveness of transcervical ablation for the treatment of symptomatic uterine leiomyomas in 147 patients (the Sonata trial). Transcervical ablation was performed on 1-10 leiomyomas per patient with leiomyoma diameters ranging from one to five cm with treated leiomyomas including all nonpedunculated types. Coprimary 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 coprimary endpoints at 12 months (N=143; full analysis set), with 64.8% of patients (95% CI 56.3-72.6%) that experienced 50% or greater reduction in menstrual bleeding and 99.3% of patients (95% CI 95.1-99.9%) were free from surgical reintervention. The mean pictorial blood loss assessment chart score decreased by 38.9%, 48.4%, and 51.1% at three, six, and 12 months, respectively ($P < .001$), and 95.1% of patients experienced a reduction in menstrual bleeding at 12 months. There were mean improvements in symptom severity and health-related quality of life of 32.1 points and 43.7 points, respectively, at 12 months (all $p < .001$). Mean maximal leiomyoma volume reduction per patient was 62.4% ($p < .001$). 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 study was limited by the lack of randomization and lack of a comparator. Miller and Osman (2019) reported on the two year results ($n=125$) of the Sonata trial. The symptom severity score (SSS) decreased from 55 ± 19 to 24 ± 18 ($p < .001$), health-related quality of life (HRQL) increased from 40 ± 21 to 83 ± 19 ($p < .001$), and EuroQol 5-Dimension scores increased from 0.72 ± 0.21 to 0.89 ± 0.14 ($p < .001$). Overall treatment satisfaction at two years was 94%. Percentage of missed work time, overall percentage of work impairment, and reductions in the percentage of activity impairment due to fibroid symptoms were all significantly reduced ($p < .001$). Through two years, surgical reintervention for heavy menstrual bleeding was performed in 5.5% of patients.

Garza-Leal et al. (2019) reported on long-term (> 5 years) clinical outcomes of transcervical radiofrequency ablation of uterine fibroids, the VITALITY study, a retrospective, single-arm, long-term data-collection study, one arm of the above FAST-EU trial. The study included 23 women with heavy menstrual bleeding secondary to fibroids were treated with transcervical radiofrequency ablation guided by integrated intrauterine sonography (using the Sonata® System). This study was within one center of the 12-month Fibroid Ablation Study-EU clinical trial. 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. Seventeen women (73.9%) provided long-term follow-up information, with a mean of 64.4 months ± 4.5 months (range: 57-73 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 ($p = 0.002$, and $p = 0.0001$, 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. Freedom from surgical reintervention at 1, 2, and 3 years was 100%, and, at 4 and 5 years, was $88.2\% \pm 7.8\%$. There was a single pregnancy occurring within the first year of treatment leading to a normal-term delivery by elective repeat cesarean section. The study is limited by the lack of randomization and small number of participants.

Taheri et al. (2019) conducted a systematic review to examine 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 included: 52 related to UAE, 11 to RFA, 17 to FUS, and one compared UAE and FUS. The report noted the published uterine volume and fibroid volume changes in the studies at one 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 with fibroid volume reduction most marked with RFA; with UAE resulting in the next most volume reduction. The authors note that additional larger cohort studies, including those that are randomized and/or comparative, would enable definitive conclusions.

Initial evidence on the safety and efficacy of transcervical intrauterine ultrasound-guided RFA for the treatment of uterine fibroids included a study of the VizAblate system: the single-arm FAST-EU trial of the VizAblate System

conducted at 7 centers outside the U.S. (Bongers et al., 2015; Brölmann et al., 2015; Huirne and Brooks, 2018). VizAblate is the previous version of the Sonata System; the two systems are similar.

Professional Societies/Organizations

American Association of Gynecological Laparoscopists (AAGL):

The AAGL published practice guidelines for the diagnosis and management of submucous leiomyomas (2012) which note with currently available evidence, embolic and ablative therapies, including leiomyoma ablation with radiofrequency electricity are not appropriate for women with submucous myomas who have current infertility or who wish to conceive in the future. The guidelines do not address embolic or ablative therapies related to submucous myomas for individuals without infertility or who do not desire future conception.

Professional organization guidelines for transcervical intrauterine ultrasound-guided RFA for treatment of uterine fibroids are lacking.

Use Outside of the US

Canadian Agency for Drugs and Technologies in Health (CADTH): CADTH published a systematic review of the clinical and cost-effectiveness for uterine-preserving interventions for the management of symptomatic uterine fibroids. The review assessed the treatment effects of various uterine-preserving interventions in women with symptomatic uterine fibroids including myomectomy, uterine artery embolization (UAE), uterine artery occlusion (UAO), magnetic resonance-guided focused ultrasound (MRgFU), and radiofrequency volumetric thermal ablation (RFVTA). These interventions were compared either with the conventional surgical intervention (hysterectomy), or with other uterine-preserving interventions. It was concluded that radiofrequency volumetric thermal ablation (RFVTA) improved abnormal uterine bleeding and quality of life (QOL) compared with baseline assessments. In comparison with myomectomy (in one study), RFVTA resulted in fewer complications, including intraoperative blood loss and a shorter length of stay; however, RFVTA was associated with more reinterventions.

National Institute for Health Care Excellence (NICE): NICE (2021) published an interventional procedures guidance on the use of transcervical ultrasound-guided radiofrequency ablation for symptomatic uterine fibroids. Their recommendations state that the evidence raises no major safety concerns, but it is limited in quality.

Society of Obstetricians and Gynaecologists of Canada (SOGC): SOGC published evidenced-based guidelines for the management of uterine leiomyomas (Vilos, et al., 2015). The recommendations note that, “Of the conservative interventional treatments currently available, uterine artery embolization has the longest track record and has been shown to be effective in properly selected patients. (II-3) Newer focused energy delivery methods are promising but lack long-term data. (III)”. The newer methods included in this this statement includes radiofrequency ablation of uterine fibroids.

Medicare Coverage Determinations

	Contractor	Policy Name/Number	Revision Effective Date
NCD		No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

- Note:** 1) This list of codes may not be all-inclusive.
 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency

***Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.**

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