Medical Policy Reference Manual
Medical Policy

7.01.125 Radiofrequency Ablation of Uterine Fibroid Tumors (Leiomyomata)

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Description

Uterine fibroids, also known as leiomyomata, are common benign tumors of the uterus. While often asymptomatic, fibroids can produce a variety of symptoms, including abnormal bleeding, pain, pressure, infertility, miscarriage, constipation, urinary frequency, and painful sexual intercourse. Symptomatic fibroids can be medically managed with hormone therapy and analgesics, and surgical procedures such as hysterectomy and myomectomy. Uterine artery embolization is effective for certain fibroids as well. Hysterectomy is the most curative treatment but has a longer hospitalization period. Myomectomy is more uterus-sparing with a shorter hospitalization and recovery period. Uterine artery embolization (UAE) is minimally invasive and generally effective over short to intermediate terms, but a hysterectomy may eventually be necessary.

Radiofrequency volumetric thermal ablation (RFVTA) has been investigated as an alternative to hysterectomy and myomectomy in the treatment of symptomatic uterine fibroids. This is a minimally invasive laparoscopic system performed using ultrasound guidance. The surgeon first inserts the ultrasound probe, then performs a precise mapping of the uterus, identifying and locating all fibroids that may not have been seen on external ultrasound. The tumors can be examined from any angle. Then the surgeon deploys the radiofrequency probe into the tumor and applies electrical current. Internal monitoring devices constantly monitor voltage in the probe and temperature of the tissue, and the generator adjusts the current as needed to maintain constant temperature. This technique allows multiple tumors to be treated in the same session. The procedure is performed under general anesthesia; most patients return to normal activities in 4 to 5 days.

Policy

Radiofrequency ablation (i.e. Acessa™, Sonata®) for the treatment of symptomatic uterine fibroid tumors is considered **medically necessary** as an alternative to hysterectomy or myomectomy **when one or more of the following symptoms** attributed to uterine fibroids **are present**:

- Excessive/profuse menstrual bleeding (Menorrhagia) with or without anemia; OR
- Pelvic pain (i.e. acute severe pain; chronic lower abdominal pain; low back pressure); OR
- Urinary symptoms related to compression of the ureter or bladder (not due to urinary tract infection); AND / OR
- Dyspareunia

Radiofrequency ablation (i.e. Acessa™, Sonata®) for the treatment of uterine fibroid tumors is **considered experimental / investigational** for the purpose of preserving childbearing potential for women with uterine fibroids and for all other indications not specified above.

Policy Guidelines

Rationale:

1. The technology must have final approval from the appropriate U.S. government regulatory bodies:

The Acessa™ system (Halt Medical, Inc.) received FDA clearance under the 510(k) process in November of 2012, as a next-generation device comparable to the Halt 2000GI system, which was cleared in 2010. The 2000GI system labeling was for use in percutaneous, laparoscopic and intraoperative coagulation and ablation of soft tissue. The Acessa™ system bears the same labeled indication, with the specific inclusion for treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. The ultrasound guidance devices have received separate 510(k) clearances.

2. The scientific evidence must permit conclusions concerning the effect on health outcomes:
Six published prospective studies (n=31 to 135) have evaluated the Acessa™ system. Of these, two studies (Guido, 2013 and Berman et al, 2014) reported 2 and 3-year outcomes respectively. There was one randomized controlled trial (RCT), that of Brucker (2014). A multicenter international prospective study (Chudnoff et al, 2013) reported on the safety and efficacy of RFTVA in a total of 135 premenopausal women with symptomatic fibroids. Investigators were chosen who had no financial interest in the results. Although there were considerable subjective data, these data reported a high rate of satisfaction with the procedure, improvements in quality of life, and reduction of symptoms. There was one adverse event, and one patient lost to follow-up. This was the group of patients who were followed for 2- and 3-year durability of treatment as a prospective cohort study. After 3 years, 14 patients had required hysterectomy. The RCT randomized 25 patients to RFTVA and 25 to laparoscopic myomectomy (LM). Blood loss and hospital stay were higher in the LM group. Duration of the procedures were comparable. The results met criteria for noninferiority of RFTVA to LM, but long-term results are not yet available for this study.

The available studies provide preliminary evidence that warrants further study in well-designed clinical trials comprised of an adequate number of subjects. Of the limited studies available, most were small, uncontrolled, and non-randomized. The RCT was a small study that calls for additional trials. Overall the evidence available does not permit conclusions regarding health outcomes.

3. The technology must improve the net health outcome:

The results, while not robust report mostly subjective improvements in symptomatic patients with uterine fibroids treated with Acessa™, with sustained reduction of menstrual blood loss at all time points at up to 36 months. Although the studies are few in number and involve small numbers of patients, treatment subjectively reduced pain, heavy bleed and other symptoms consistently with improved quality of life. Treatment is done on an outpatient basis with an acceptable safety profile. As the evidence is too limited to permit conclusions on patient outcomes, there is insufficient evidence to judge whether the net health outcomes are improved.

4. The technology must be as effective as any established alternatives:

The evidence is limited, but in the small RCT, RFTVA appeared to be non-inferior to myomectomy for patients who prefer a uterus-sparing procedure. However, the study was too small and of relatively short follow-up. Additional comparative type studies are needed to establish whether the outcomes from RFVTA are at least comparable to those from more established treatments. RFVTA is intended mainly for patients who wish to avoid hysterectomy who are no longer concerned about child-bearing; there were no studies designed to evaluate Acessa™ RFVTA for patients who desire to retain child-bearing ability.

5. The improvement must be attainable outside the investigational settings:

RFVTA currently is not widely used, but more widespread adoption of the technique can be anticipated. It is not known based on the available evidence whether net improvements in health outcomes can be expected outside of the investigational settings.

2017 Update:

A search of the peer-reviewed literature was performed for the period January 2015 through January 2017. Findings in the recent literature do not change the policy statement. Clinical trials regarding Radiofrequency Ablation of Uterine Fibroid Tumors (Leiomyomata) are ongoing. The treatment remains experimental / investigational.

2019a Update:

A search of the peer-reviewed literature was performed for the period of February 2017 through February 2019. Findings in the recent literature do not change the conclusion on the use of radiofrequency ablation for the treatment of uterine fibroids tumors (leiomyomata). Therefore, the Policy statement remains experimental / investigational.

2019b Update:

The policy statement was revised to reflect that radiofrequency ablation of uterine fibroid tumors (i.e. Acessa™) is considered a medically necessary alternative to hysterectomy or myomectomy when criteria are met.

The Acessa™ System:

1. The technology must have final approval from the appropriate U.S. government regulatory bodies:

   In 2012, The Acessa™ system received clearance from the FDA through the 510(k) process for percutaneous laparoscopic coagulation and ablation of soft tissue, and for the treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance (K121858). An earlier comparable version (Halt 2000GI™ Electrosurgical Radiofrequency Ablation System) of the technology was previously approved in 2010. Subsequent separate 510(k) clearances have been issued for the ultrasound guidance devices and more recently (2018), a third-generation version, Acessa™ ProVu System® was cleared for marketing by the FDA for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance (K181124).

2. The scientific evidence must permit conclusions concerning the effect on health outcomes:

   Evidence evaluating the safety and efficacy of RFVTA with the Acessa™ system includes four clinical studies that have been reported in several publications with sample sizes ranging from 31 to 135. Studies include a single-center comparative RCT reported in several publications (Brucker et al. 2014, Hahn et al., 2015 & Kramer et al., 2016), and noncomparative, prospective studies (Garza Leal et al., 2011, Robles et al., 2013, Chudnoff et al., 2013, Galen et al., 2013, Guido et al., 2013, & Berman et al., 2014). The RCT (N=50) was conducted in Germany and compared RFVTA with laparoscopic myomectomy for the treatment of uterine. Findings from the RCT suggest RFVTA is noninferior to laparoscopic myomectomy in terms of length of hospital stay (10 vs 29.9 hours, $p<0.001$). Findings on symptoms and QOL were similar for the two groups (RFVTA vs Laparoscopic myomectomy) post-procedure through 2 years follow-up. Lin et al. (2018) assessed the short- and long-term impact of RFVTA on symptom relief and quality of life. The review included 8 studies (1 RCT and 7 non-comparative trials, N=581) for which the authors found that at 12 months following the procedure, symptom severity scores improved significantly, and quality of life improved significantly through 24 months in most studies and up to 36 months post-procedure in 1 study. The risk for recurrence based on a weighted mean follow-up of 24.65 months (range, 3-36 months) was 4.4%. Reintervention rates across studies ranged from 0 to 12% and included dilation and curettage for hypermenorrhea, uterine artery embolization, hysterectomies, and myomectomies. Procedural-related adverse events for RFVTA were uncommon and examples included hypermenorrhea, vertigo, abdominal pain, urinary tract infection, abdominal wall injury, pelvic abscess, laceration of sigmoid colon, vaginal bleeding, uterine serosal burn, and severe hemorrhaging during cesarean section and early postpartum period. Furthermore, data on reproductive outcomes are limited.

3. The technology must improve the net health outcome:

   The overall body of evidence on RFVTA with the Acessa™ system is of low quality due to the small/limited sample sizes and poor design (small, uncontrolled and non-randomized). While study findings so far appear promising and favor RFVTA with the Acessa™ system at improving symptom and quality of life, additional well-designed studies with large sample sizes are needed. The current body of evidence although suggestive of improvements in the net health outcome (i.e. improvements in symptoms, quality of life, low reintervention rates, and procedural-related adverse events) does not permit conclusions on an effect on the net health outcome.

4. The technology must be as effective as any established alternatives:

RFVTA with the Acessa™ system was compared with laparoscopic myomectomy in 1 study (the RCT) and while the system was found to be non-inferior to myomectomy in terms of length of hospital stay, both RFVTA and myomectomy were generally found to be similar in terms symptom and quality of life.

5. The improvement must be attainable outside the investigational settings:

   Improvements in the investigational settings have not been well established due to studies of overall limited quality however, findings are promising and suggests improvements may be attainable in conditions of everyday practice.

2020 Update:

The policy statement was revised to reflect that radiofrequency ablation of uterine fibroid tumors (i.e. Sonata®) is considered a medically necessary alternative to hysterectomy or myomectomy when criteria are met.

The Sonata® System:

1. The technology must have final approval from the appropriate U.S. government regulatory bodies:

In August 2018 Gynesonics, Inc. received clearance for marketing the Sonata® Sonography-Guided Transcervical Fibroid Ablation System. Clearance was granted via the FDA 510(k) process (K173703). The indicated use is for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding. The primary predicate device on which the approval was granted is the Acessa System.

2. The scientific evidence must permit conclusions concerning the effect on health outcomes:

In a prospective, single-arm, multi-center, interventional trial, Chudnoff and colleagues (2019) evaluated the 12-month safety and effectiveness of trans-cervical RFA ablation for the treatment of symptomatic uterine leiomyomas. In this industry-sponsored study, 95.1% of participants experienced a reduction in menstrual bleeding at 12 months. There were significant mean improvements in symptom severity. Mean maximal leiomyoma volume reduction per patient was 62.4%. More than 5% 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 (AEs). The authors concluded that trans-cervical ablation was associated with a significant reduction in leiomyoma symptoms with no device-related problems and a low surgical re-intervention rate through 12 months, demonstrating its potential to safely and effectively treat all non-pedunculated leiomyoma types through a uterus-conserving, incisionless approach.

Lin et al (2018) conducted a meta-analysis of improvement in symptom severity, QOL, and reintervention after RFVTA. The review included one RCT and seven non-comparative trials. The recurrence risk at a mean follow-up of 24.65 months (range, 3 to 36 months) was 4.4%. Improvements in symptoms and QOL were maintained out to 24 months in 3 studies and out to 36 months in 1 study. No studies were identified that had follow-up longer than 36 months.

3. The technology must improve the net health outcome:

The pivotal SONATA investigational device exemption (IDE) trial demonstrated statistically significant symptom relief, improved quality of health outcomes, zero device-related adverse events, and high patient satisfaction with a low rate of surgical reintervention (Chudnoff 2019). Notably, the follow-up period for this study was 12-months.

4. The technology must be as effective as any established alternatives:

Alternatives for treating uterine fibroids include hysterectomy, myomectomy, uterine artery embolization, and hormonal preservation. There is patient preference for less invasive therapies that preserve the uterus. A systematic review and meta-analysis by Sandberg et al (2018) evaluated the risk of reintervention for hysterectomy and QOL after uterine-sparing interventions for fibroids. Risk of reintervention at 12 months was 0.3% for RFVTA compared with 3.6% for UAE and 1.1% for myomectomy. Symptom severity and QOL scores were similar for the three treatments. In the Chudnoff (2019) study there was a decrease in pain and bleeding, an increase in

satisfaction, and an increased rate of recovery compared to established alternatives like hysterectomy or myomectomy.

A systematic review performed by Bradley et al (2019) compared studies of radiofrequency fibroid ablation using three different approaches: laparoscopic, transvaginal, or transcervical. Nineteen articles were identified that used a laparoscopic approach, eight articles used a transvaginal approach and five articles used a transcervical approach. When compared with laparoscopic RFA, transcervical RFA was associated with a brief mean procedure time, short mean length of stay and a faster (on average) return to normal activities and work.

5. The improvement must be attainable outside the investigational settings:

The Sonata® System is used routinely with good results. As shown by the Chudnoff 2019 study, there was a decrease in pain and bleeding, an increase in satisfaction, and an increased rate of recovery compared to established alternatives like hysterectomy or myomectomy. As such, the improvement is attainable outside the investigational settings.

2021 Update:

A search of the peer-reviewed literature was performed for the period of November 2020 through February 2021. Findings in the recent literature do not change the medically necessary and experimental/investigational statements in the Policy section.

Cross References to Related Policies and Procedures

Uterine Artery Embolization for Fibroid Tumors (Leiomyomata) Medical Policy 4.01.008
Focused Ultrasound Ablation of Uterine Fibroids Medical Policy 6.01.033

References

The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own and may or may not be in agreement with those of CareFirst.

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