

Clinical Policy: Radiofrequency Ablation of Uterine Fibroids

Reference Number: CP.MP.187

Date of Last Review: 02/22

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Uterine leiomyomas are the most common solid pelvic tumors in women and the leading indication for hysterectomy. Many women seek an alternative to hysterectomy as they desire future childbearing or wish to retain their uteri. As alternatives to hysterectomy become increasingly available, it is important to understand the efficacies and risks of these treatments.¹ This policy describes medical necessity criteria for radiofrequency ablation (RFA) of uterine fibroids.

Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation[®] that laparoscopic radiofrequency ablation (the Acessa[™] System) of uterine fibroids is medically necessary when all the following criteria are met:
 - A. Procedure will be done under laparoscopic ultrasound guidance following manufacturer instructions;
 - B. Member/enrollee is not pregnant or nursing;
 - C. A cardiologist has been consulted if a pacemaker is present.

- II. It is the policy of health plans affiliated with Centene Corporation that there is insufficient evidence in the published peer-reviewed literature to support the safety and effectiveness of transcervical radiofrequency ablation (i.e., the Sonata system (Gynesonics)) for the treatment of uterine fibroids.

Background

According to the American College of Obstetricians and Gynecologists (ACOG), uterine fibroids (UF), also called leiomyomas or myomas, are benign growths that may be inside the uterus, on the outer surface, within the wall or attached by a stem-like structure. Uterine fibroids are most common in women aged 30-40 and occur more frequently in African American women than white women. They are typically detected during a routine pelvic exam.^{1,7}

Although many women with UFs are asymptomatic, common symptoms include changes in menstruation, cramping, bleeding at times other than during menstruation, pelvic pressure, pain in the abdomen or lower back, and pain during sex. Women may also experience difficult or frequent urination or constipation and painful bowel movements. UFs can cause an enlarged uterus and abdomen and lead to miscarriages or infertility.^{1,7}

Non-surgical treatment for uterine fibroids includes pharmaceutical options such as hormonal contraceptives, nonsteroidal anti-inflammatory drugs, gonadotropin-releasing hormone agonists, progesterone modulators and aromatase inhibitors. Surgical options include myomectomy, the surgical removal of fibroids (which spares the uterus) and hysterectomy, which is the definitive treatment, eliminating the possibility of recurrence.^{1,7}

CLINICAL POLICY

Radiofrequency ablation of uterine fibroids

Recently, radiofrequency ablation (RFA) has been introduced as alternative treatment for uterine fibroids. RFA uses hyperthermic energy with real-time ultrasound and can be delivered by a laparoscopic, transvaginal, or transcervical approach. Currently there are two systems for RFA, the Acessa[™] system and the Sonata[®] system.

The Acessa[™] Procedure is a minimally invasive, uterine sparing, outpatient treatment for fibroids found within the uterine wall. Using radiofrequency ablation to destroy each fibroid by applying controlled energy through a small needle, the Acessa Procedure does not affect surrounding tissues and allows for multiple fibroids to be treated through a single laparoscopic uterine puncture. Additionally, the generator also performs electrocautery to stop bleeding. The body ultimately reabsorbs the destroyed tissue following the procedure.^{2,3}

The Sonata[®] System combines real-time intrauterine ultrasound guidance with targeted radiofrequency ablation in an incisionless procedure to treat symptomatic uterine fibroids through a transcervical approach. The system also includes a graphical guidance software that provides the operating gynecologist with real-time graphic overlay on the live ultrasound image.^{4,5}

Regarding the Acessa procedure, Hayes states, in general, a low-quality body of evidence derived from 6 studies (published in 11 articles) suggests that radiofrequency volumetric thermal ablation (RFVTA) may result in improved symptoms and some improvements in general quality of life assessments from baseline. Comparative effectiveness evidence comparing RFVTA with alternative uterine-sparing fibroid treatments is insufficient to draw conclusions. In general, statistically significant differences were not noted in most outcomes; however, comparative analyses were limited to one to two randomized controlled trials and were not always conducted statistically. No studies evaluated success in achieving pregnancy among women attempting to conceive after RFVTA. Three studies limited the eligible patient populations to women who had no desire to maintain fertility. Furthermore, the efficacy of RFVTA for fibroids of varying International Federation of Gynecology and Obstetrics classification was evaluated by only one study. 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.²

A Hayes statement on the Sonata procedure finds a very-low-quality body of evidence that is insufficient for drawing conclusions regarding the efficacy and safety of transcervical RFA for symptomatic UF. Compared with pretreatment status, the Sonata procedure was associated with statistically significant improvements in symptoms, quality of life, and fibroid volume. Due to the limited number of studies, consistency of results cannot be determined. Additional studies comparing the Sonata procedure with established treatments for UF are needed to determine whether the Sonata procedure provides meaningful clinical benefits relative to currently available options. All 3 studies excluded women with an intent for future fertility; however, 2 studies reported that 1 woman in each study conceived, carried to term, and delivered infants.⁴

American College of Obstetricians and Gynecologists

CLINICAL POLICY

Radiofrequency ablation of uterine fibroids

The American College of Obstetricians and Gynecologists (ACOG) states that although RFA is reasonable option to consider for the treatment of symptomatic uterine leiomyomas, access to this technology is currently limited. The society also notes that even though RFA can be delivered by laparoscopic, transvaginal or transcervical approach, the laparoscopic approach has been studied the most rigorously.⁷

They go on to state that although laparoscopic RFA with a leiomyoma-specific FDA approved device has been studied primarily in nonrandomized trails, two recent meta-analyses summarize long-term data on the use of RFA to treat a wide variety of leiomyoma types and sizes. In these two meta-analyses, uterine leiomyoma volume reduction ranged from 32% to 66% at 12 months, and 77% at greater than 12 months follow up. The cumulative rate of postoperative surgical reintervention for leiomyoma-related symptoms was 4.2%, 8.2% and 11.5% at 1, 2, and 3 years, respectively. Both statistically and clinically significant improvements were observed in health-related quality of life and symptom severity in long-term follow up. Complication reporting was highly inconsistent, but no serious procedural complication such as death or injury to visceral structures was reported in any study. Neither meta-analysis reported outcomes on menstrual bleeding.

Additionally, in a case-series of 30 pregnancies after laparoscopic RFA, there were 26 full-term live births and four pregnancy losses. There were no cases of preterm delivery, uterine rupture, placental abruption, placenta accreta, or intrauterine growth restriction, but due to the small sample size there was no definitive conclusion about risk or incidence of pregnancy complications.⁷

ACOG recommends that laparoscopic radiofrequency ablation (RFA) can be considered as a minimally invasive treatment option for management of symptomatic leiomyomas in patients who desire uterine preservation and are counseled about the limited available data on reproductive outcomes.⁷

Coding Implications

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CPT Codes	Description
58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency

CLINICAL POLICY
Radiofrequency ablation of uterine fibroids

HCPCS Codes	Description
0404T	Trans cervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency

Reviews, Revisions, and Approvals	Revision Date	Approval Date
WellCare’s HS-213 Radiofrequency Ablation of Uterine Fibroids policy adopted. Changed radiofrequency ablation of uterine fibroids to experimental/investigational.	04/20	04/20
“Experimental/investigational” verbiage replaced in policy statement with descriptive language. References reviewed and updated. All instances of “member” changed to “member/enrollee.”	04/21	04/21
Annual review. References reviewed and updated. Changed, "Last Review Date," in header to, "Date of Last Review," and "Date," in revision log to, "Revision Date." Policy updated with medical necessity criteria for laparoscopic RFA (Acessa). Insufficient evidence statement now only applies to transcervical radiofrequency ablation (Sonata). Background updated to include ACOG updates. Reviewed by specialist.	02/22	02/22

References

1. The American College of Obstetricians and Gynecologists. Frequently asked questions: Uterine Fibroids. <https://www.acog.org/womens-health/faqs/uterine-fibroids>. Published December 2018. Accessed February 8, 2022.
2. Laparoscopic radiofrequency volumetric thermal ablation (Acessa System; Halt Medical Inc.) for treatment of uterine fibroids. Hayes. www.hayesinc.com. Published December 20, 2019 (annual review March 4, 2021). Accessed February 8, 2022..
3. Acessa Product Page. <https://gynsurgicalsolutions.com/patients/treatment-options/acessa/procedure-steps-and-components/> February 8, 2022.
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5. Sonata[®] Treatment. Gynesoncis, Inc. <https://sonatatreatment.com/for-physicians/the-sonata-system/>. Accessed February 8, 2022.
6. Stewart, EA. Uterine fibroids (leiomyomas): Treatment overview. UpToDate. www.uptodate.com. Published August 6, 2021. Accessed February 8, 2022.
7. American College of Obstetricians and Gynecologists’ Committee on Practice Bulletins–Gynecology. Management of Symptomatic Uterine Leiomyomas: ACOG Practice Bulletin, Number 228. *Obstet Gynecol.* 2021;137(6):e100-e115. doi:10.1097/AOG.0000000000004401

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program

CLINICAL POLICY

Radiofrequency ablation of uterine fibroids

approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take

CLINICAL POLICY

Radiofrequency ablation of uterine fibroids

precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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