

# Clinical Policy: Radiofrequency Ablation of Uterine Fibroids

Reference Number: CP.MP.187

Last Review Date: 04/21

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## 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 because 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.<sup>1</sup> This policy describes medical necessity criteria for radiofrequency ablation of uterine fibroids.

## Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that there is insufficient evidence in the published peer-reviewed literature to support the safety and effectiveness of radiofrequency ablation and the use of the Acessa<sup>™</sup> and Sonata<sup>®</sup> Systems 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 develop from the muscle tissue of the uterus. These growths can vary greatly in size, shape, and location. Uterine fibroids are common and estimated to affect 70% of white women and 80% of black women by age 50 years. They are typically detected during a routine pelvic exam.<sup>1,2</sup>

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. Fibroids can cause an enlarged uterus and abdomen and lead to miscarriages or infertility.<sup>1,2</sup>

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. Myomectomy may be performed abdominally, laparoscopically or hysteroscopically depending on the size, number and location of the fibroids.<sup>1,2</sup>

Recently, radiofrequency ablation (RFA) has been introduced as alternative treatment for uterine fibroids. Currently there are two systems for RFA, the Acessa<sup>™</sup> system and the Sonata<sup>®</sup> system.

The Acessa<sup>™</sup> 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<sup>™</sup> Procedure does not affect surrounding

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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.<sup>3,4</sup>

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.<sup>3</sup>

The Sonata<sup>®</sup> System combines real-time intrauterine ultrasound guidance with targeted radiofrequency ablation in an incisionless procedure to treat symptomatic uterine fibroids. The system also includes a graphical guidance software that provides the operating gynecologist with real-time graphic overlay on the live ultrasound image.<sup>5,6</sup>

Regarding the Sonata procedure, Hayes states, a very-low-quality body of evidence is insufficient to draw 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.<sup>5</sup>

**Coding Implications**

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

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

Reviews, Revisions, and Approvals	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

#### References

1. Alternatives to Hysterectomy in the Management of Leiomyomas. Practice Bulletin Number 96 (Replaces Practice Bulletin Number 16, May 2000 and Committee Opinion Number 293, February 2004. Reaffirmed 2019) The American College of Obstetricians and Gynecologists. [www.acog.org](http://www.acog.org). Published August 2008. Accessed April 7, 2021.
2. Uterine fibroids. Frequently asked questions: Gynecologic Problems. The American College of Obstetricians and Gynecologist. [www.acog.org](http://www.acog.org). Accessed March 17, 2021.
3. Laparoscopic radiofrequency volumetric thermal ablation (Acessa System; Halt Medical Inc.) for treatment of uterine fibroids. Hayes website [www.hayesinc.com](http://www.hayesinc.com). Published December 20, 2019 (annual review March 4, 2021). Accessed March 17, 2021.
4. Acessa™ System. Halt Medical, Inc. Web site. <http://www.acessaprocedure.com/healthcare-professionals/>. Accessed March 17, 2021.
5. Transcervical radiofrequency ablation with the Sonata System for symptomatic uterine fibroids. Hayes website [www.hayesinc.com](http://www.hayesinc.com). Published September 30, 2020. Accessed April 7, 2021.
6. Sonata® Treatment. Gynesoncis, Inc. Website <https://sonatatreatment.com/for-physicians/the-sonata-system/>. Accessed April 2, 2020.
7. Stewart, EA. Overview of treatment of uterine leiomyomas (fibroids). In: UpToDate. Barbieri RL and Chakrabarti A, Eds. Published January 4, 2021. Accessed March 17, 2021.

#### **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 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

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

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**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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