# VHA Office of Integrated Veteran Care
# Clinical Determination and Indication
# Ultrasound-Guided Radiofrequency Ablation
# for Symptomatic Uterine Fibroids

**CDI Number: 00010**

**Original Effective Date: June 01, 2024**

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## I. Disclaimer

This document is currently in draft and is intended to be used as a reference for non-VA providers and not intended to replace clinical judgment when determining care pathways. These guidelines do not guarantee benefits or constitute medical advice.

## II. Clinical Determinations and Indications

### a. Indications for Ultrasound-Guided Radiofrequency Ablation

Ultrasound-guided radiofrequency ablation (RFA) for the treatment of symptomatic uterine fibroids is considered **medically necessary** when **ALL** the following criteria are met:

- Veteran is 18 years of age or older
- Currently not pregnant
- Fibroids are no greater than 7 cm in any diameter
- Uterine size does not exceed 14 cm on ultrasound
- Low suspicion of leiomyosarcoma

AND

- The individual has persistence of **one or more symptoms** attributable to uterine fibroids such as but not limited to:
    - Excessive uterine bleeding as evidenced by either profuse or prolonged bleeding
    - Anemia due to acute or chronic blood loss
    - Pelvic discomfort caused by myomas, manifesting as acute, severe pain, chronic lower abdominal pain, dyspareunia, low back pressure or bladder pressure with urinary frequency not due to a urinary tract infection

The laparoscopic and transcervical approaches are two FDA-approved options for treatment of symptomatic uterine fibroids using RFA technology. Treatment approach will be at the discretion of the obstetrician/gynecologist based on clinical judgment in the best interest of the patient.

### b. Limitations/Exclusions

For all conditions/indications not listed in section II.a. of this document, ultrasound guided RFA is considered **not medically necessary** due to insufficient evidence of efficacy and safety.

Conditions/indications for which ultrasound-guided RFA for the treatment of symptomatic fibroids is **not medically necessary** include, but are not limited to the following:

- Diagnosis of cancer or precancerous lesions anywhere in the pelvis
- A diagnosis of, or high risk for, leiomyosarcoma
- Fibroids greater than 7 cm in diameter
- Uterine size greater than 14 cm
- Currently pregnant
- Active pelvic inflammatory disease
- Active pelvic infection
- Coagulopathy
- Adhesive disease involving the uterus
- Veterans with Essure or IUD (unless IUD removed)
- Other non-gynecologic metal devices in the pelvis (unless removed)

### c. Description of Treatment

**Transcervical Ultrasound-Guided Radiofrequency Ablation**

Transcervical ultrasound-guided RFA is a minimally invasive procedure used to treat symptomatic uterine fibroids with the Sonata System. This incisionless technique combines real-time intrauterine ultrasound guidance with targeted RFA, through the cervix, to treat symptomatic uterine fibroids, significantly reducing their size. The system also includes graphical guidance software that provides the operating gynecologist with real-time graphic overlay on the live ultrasound image.

The procedure is typically performed in an outpatient setting under local or general anesthesia. The cervix is dilated, a thin catheter is inserted into the uterus and guided to the location of the fibroid using an ultrasound. Once the catheter is in place, the fibroid is targeted with radiofrequency energy, destroying the fibroid tissue. The ablation instrument is then removed, and the procedure is complete. The destroyed tissue is then gradually absorbed by the body over time.

Transcervical ultrasound-guided RFA is an effective alternative to traditional surgical treatments for symptomatic uterine fibroids such as a hysterectomy or myomectomy. It offers a shorter recovery time, fewer complications, minimal scarring, and is a preferred treatment for patients who want to preserve their uterus. Impact of ultrasound-guided RFA on future pregnancy

is unknown, however, successful pregnancies have been documented after use of the Sonata System.

### Laparoscopic Ultrasound-Guided Radiofrequency Ablation

Laparoscopic ultrasound-guided RFA is a minimally invasive procedure used to treat symptomatic uterine fibroids with the Acessa system. The procedure involves using radiofrequency energy to destroy the fibroid tissue in the uterus by applying controlled energy through a small needle, with minimal impact to surrounding tissues. This technique may target multiple fibroids through a single laparoscopic uterine puncture.

The procedure is performed under general anesthesia in an outpatient setting. The surgeon makes a small incision in the abdomen and inserts an instrument called a laparoscope, providing a visual guide for the procedure. Next, an ultrasound probe is inserted through another small incision in the abdomen, allowing the surgeon to visualize the fibroids and surrounding tissue. A thin flexible needle is then guided through the ultrasound probe and into the fibroid. Once the needle is in place, radiofrequency energy is applied, heating the fibroid, and destroying the tissue.

Both systems use radiofrequency currents at 460 kHz delivered through an electrode array using ultrasound-guidance to target lesions. Incorporated software with the systems calculates ablation times according to the size of targeted tissue.

## III. Background and Supporting Information

The following information is for reference purposes only in accordance with the medical benefits package outlined in 38 C.F.R. § 17.38 (b). Each subsection supports VA's determinations for medical necessity and alignment with generally accepted standards of medical practice.

### a. Background of Uterine Fibroids

According to the American College of Obstetricians and Gynecologists (ACOG), uterine fibroids, also called leiomyomas or myomas, are almost always benign growths that develop from the muscle tissue of the uterus. These growths can vary greatly in size, shape, and location. Uterine fibroids occur most commonly in individuals with uteruses between the ages of 30-40 years, although they can occur at any age. Uterine fibroids are typically detected during a routine pelvic exam with the doctor evaluating the size and shape of the uterus.

Common symptoms of fibroids include changes in menstruation, cramping, bleeding at times other than during normal menstruation cycles, pain in the abdomen or lower back and pain during sexual intercourse. Patients may also experience difficulty with or frequent urination, constipation and/or painful

bowel movements. Fibroids may cause an enlarged uterus and abdomen and may lead to miscarriages or infertility. There are several non-surgical treatments for uterine fibroids including medication, such as birth control, gonadotropin-releasing hormone agonists and progestin. Surgical options include myomectomy, the surgical removal of fibroids while leaving the uterus in place, and in more severe cases, hysterectomy, which is the removal of the uterus.

Ultrasound-guided RFA may be delivered by a laparoscopic, transvaginal, or transcervical approach, using ultrasound guidance to apply radiofrequency waves in targeted uterine fibroids. These approaches are similarly effective in reducing uterine leiomyoma volume and in improving quality of life metrics. Significant improvements have been observed in health-related quality of life and symptom severity in long-term follow up (up to 36 months). Reporting of complication was highly inconsistent, but no serious procedural complications such as death or injury to visceral structures were reported in any of the included studies.

For patients who would like to preserve reproductive function and their uterus, ultrasound-guided RFA for the treatment for symptomatic uterine fibroids may be a safe and effective alternative to hysterectomy or myomectomy. Additional information is described in section II.d. in the description of treatment.

### b. Research, Clinical Trials, and Evidence Summaries

The ACOG provides evidence-based recommendations for the medical, procedural, and surgical management of symptomatic leiomyomas (fibroids). Many patients with symptomatic uterine fibroids seek alternative options to hysterectomy or myomectomy that may help to preserve reproductive function. This has increased interest in minimally invasive solutions such as the transcervical (e.g., the Sonata system) or the percutaneous, laparoscopic (e.g., the Acessa system) methods, which use radiofrequency energy to ablate uterine fibroids. The primary interests in both systems, Sonata and Acessa, include the noninvasive delivery method, uterine preservation, ability to treat a wide range of fibroid types, and rapid recovery and return to baseline ADLs following the procedure.

In a narrative review by Stewart et al. (2023) both laparoscopic and transcervical options provide effective treatment for symptomatic uterine fibroids in a uterine-sparing manner. Short-term outcomes for both laparoscopic and transcervical RFA treatments show short recovery times and even shorter times with the transcervical method. Data on long-term outcomes are limited and further research with larger cohorts and longer follow-up terms are needed to confirm the long-term efficacy of ultrasound-guided RFA treatments for symptomatic uterine fibroids.

Lukes et al. (2020) performed a prospective, controlled, multicenter interventional trial and studied participants who underwent the transcervical ultrasound-guided radiofrequency fibroid ablation (TRFA) procedure. The study assessed clinical outcomes over three years and found that this incisionless procedure was a preferable treatment option for those who wanted to preserve the uterus and has been shown to be safe and effective, producing durable symptom relief. Surgical reintervention was a clinical outcome measure assessed and there was evidence that showed rates remained low beyond three years following TRFA. Overall, participants treated with TRFA for symptomatic uterine fibroids experienced significant reductions of fibroid related symptoms with low surgical reintervention rates.

Miller et al. (2019) performed a 2-year study of sonography-guided transcervical fibroid ablation using the Sonata system. Patients showed a significant reduction in overall symptoms with only 5.5% needing surgical reintervention. This study indicated that patients who received this procedure had decreased symptom severity by over 50%, and health-related quality of life increased more than 50%. Treatment satisfaction at 2 years post ablation was 94%.

Berman et al. (2014) studied laparoscopic radiofrequency volumetric thermal ablation (RFVTA) over 36 months after treatment in 104 patients. They found that the health and quality of life baseline almost doubled, and symptom severity decreased by almost half from baseline. Also, the study showed a sustained relief from myoma symptoms post ablation, with only 11% needing repeated interventions.

### c. U.S. Food & Drug Administration (FDA) Information

VA generally only approves use of medical devices that have received at least FDA clearance for 510(k) Premarket Notification. The FDA has determined these Class II devices are substantially equivalent (SE) to legally marketed predicate devices and may be marketed in the U.S.

To search for devices that have received FDA 510(k) clearance or Premarket Approval (PMA), please visit the FDA Devices database.

| Information | Description |
|---|---|
| Product Name | Sonata Transcervical Fibroid Ablation System 2.2 |
| PMN Applicant | Gynesonics, Inc. |
| Address | 600 Chesapeake Drive<br>Redwood City, CA 94063 |
| Approval Date | June 17, 2021 |

| Information | Description |
|---|---|
| Approval Letter | K211535.pdf (fda.gov) |

| Information | Description |
|---|---|
| Product Name | Acessa ProVu System |
| PMN Applicant | Acessa Health, Inc. |
| Address | 7004 Bee Cave Road, Bldg. 3, Suite 200<br>Austin, TX 78746 |
| Approval Date | August 31, 2018 |
| Approval Letter | K181124.pdf (fda.gov) |

### d. Medicare Coverage Determinations

There are no available Medicare coverage determinations for transcervical and laparoscopic ultrasound-guided radiofrequency ablation. VA and Medicare are governed by separate laws and regulations; thus, VA coverage determinations may be different.

## IV. Definitions

| Term | Definition |
|---|---|
| Ablation | A procedure where a type of energy is used to remove or destroy targeted tissue in the body |
| Coagulopathy | Abnormality of blood clotting function |
| Dyspareunia | Painful sexual intercourse |
| Hysterectomy | A surgical operation where the uterus is partially or completely removed |
| Laparoscopy | A surgical procedure performed using a laparoscope, a thin fiberoptic scope that provides visual images inside the body cavity for diagnostic and surgical purposes |
| Leiomyoma | Also known as uterine fibroids<br>Leiomyomas are benign smooth muscle growths in the uterus |
| Leiomyosarcoma | A type of rare cancer that grows in the smooth muscles like the uterus |
| Lesions | An area of abnormal tissue. A lesion may not be cancerous or cancerous |
| Myomata | A non-cancerous tumor composed of muscle tissue |

| Term | Definition |
|---|---|
| Myomectomy | The removal of fibroids (noncancerous tumors) from the wall of the uterus |
| Necrosis | Death/destruction of the cells in the tissue |
| Pedunculated | A structure that has a peduncle (a stalk or stem) or is attached to another structure such as tissue or muscle |
| Percutaneous | A medical procedure in which access to inner organs or other tissue is achieved via puncture of the skin |
| Radiofrequency/Radiofrequency Volumetric Thermal Ablation (RFVTA) | A minimally invasive technique that shrinks the size of tumors, nodules or other growths in the body by using radio waves, which are electromagnetic ways that generate heat |
| Transcervical | A medical procedure performed through the cervical opening of the uterus |
| Visceral | The soft internal organs of the body, especially those contained within the abdominal and thoracic cavities |

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## VI. CDI History/Revision Information

- Explanation of changes to the CDI

| Revision Type | Date of Revision | Update(s) Made to CDI |
|---|---|---|
| | MM/DD/YYYY | |
| | MM/DD/YYYY | |