# Patient Frequently Asked Questions

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1. I’M INTERESTED IN ACESSA, WHAT’S NEXT?

Find a physician who offers Acessa on the Acessa website, then call the office to schedule an initial consultation (mention Acessa (“Assess-uh”) on the phone call). During the consultation, discuss whether Acessa as a fibroid treatment option is right for you. If it is, your physician’s office can help you determine insurance coverage or discuss self-pay options.

If you have trouble scheduling an appointment with an Acessa trained physician, you can also reach us at info@acessahealth.com.

2. IS THE ACESSA PROCEDURE COVERED BY INSURANCE?

Is the Acessa procedure covered by insurance?

Many insurance companies cover the procedure. If you are a patient who is concerned about your insurance covering Acessa, have experienced an insurance denial or have been denied access to the Acessa procedure through your commercial or Medicaid plan, we have resources for you. If you have a question you can call our Insurance Support Line: 886-473-4895 or email us at Insurance@AcessaHealth.com.

How can I check if Acessa is covered by my insurance carrier?

Laparoscopic radiofrequency ablation (Lap-RFA aka Acessa) is becoming a covered benefit by more insurance companies as patients, physicians, employers and insurance companies realize that Acessa is an important option for patients to be able to consider in their quest for the right treatment. Patients whose insurance companies do not currently cover the procedure have several options to challenge a negative prior authorization decision. The best way to find out if your insurance company covers the procedure is to contact our Insurance Support Line: 866-473-4895 or email us at Insurance@AcessaHealth.com.

If the Acessa procedure is covered by my insurance carrier, how much will it cost?

We are unable to provide an estimate because every benefit plan is different. Your insurance company and the physician’s office are the best resources to provide a price quote.

The Acessa procedure is not covered by my insurance, is there an appeals process?

We have heard from some patients that they have received incorrect information from the insurance call centers. Thus, we suggest scheduling an appointment with an Acessa trained physician and going through the formal process of prior authorization. After the initial consultation, if you are a candidate for the procedure, your physician’s office will submit a pre-authorization to your insurance for the procedure.

Is there a self-pay option?

Yes, there are physicians who offer cash, self-pay options at ambulatory surgery centers (e.g., typically less expensive than hospitals). The Acessa patient hotline can help you navigate which physicians offer self-pay options.

How much does self-pay cost?

Based on data on file, the typical range is $9,000 - $15,000. The cost varies by the physician, location (hospital or surgery center) and region. The best way to get self-pricing information is to call your physician’s office and request quote information. For some offices, an initial consult is needed before the office can provide a price quote.
3. WHO IS A CANDIDATE FOR THE PROCEDURE?

**Can Acessa treat large fibroids?**
It is your doctor’s decision to decide if he or she can safely and effectively treat your fibroids. The safety and effectiveness of the Acessa procedure has not been evaluated in women with uterine size greater 14 weeks\(^1\) (which roughly equates to a single ~9 cm diameter fibroid).\(^{17,18,19}\)

**Is there a limit to the number or quantity of fibroids that can be treated?**
A physician can treat any number of fibroids present\(^1\). The number of fibroids that a physician is able to treat in a single procedure may vary. However, the ability to treat more fibroids thanks to laparoscopic ultrasound image can be an advantage of Acessa compared to myomectomy.\(^4,12\)

**Can Acessa be used to treat any type of fibroid in any location?**
Acessa can be used to treat almost all types of symptomatic uterine fibroid types, including subserosal, intramural, transmural, and submucosal.\(^1\) Acessa should not be used on non-uterine masses.

**How can I figure out what types of fibroids I have?**
Typically, physicians determine the type of fibroids and locations using an MRI or transvaginal ultrasound (TVUS), when determining diagnosis and treatment plan. If you have already received an MRI or ultrasound, but do not know what type of fibroids or the location of your fibroids, we encourage you to ask your doctor for a written list of types and locations of the fibroids.

**Is there an age limit?**
Most women who seek the surgery are pre-menopausal. Acessa studied women 25 years and older. The study population included women up to 55 years old.\(^1\) As a reminder, Acessa is a treatment for benign (non-cancerous) symptomatic fibroids. If patients are at risk for cancer, or malignancy, Acessa is not the appropriate treatment.

**Is Acessa recommended for women who want to have future pregnancies?**
Insufficient data exists to evaluate the safety and efficacy of the Acessa Procedure for women who are seeking future pregnancy. Therefore, the Acessa Procedure is not recommended for women who are planning future pregnancy.\(^3\) Fertility discussions should be had with physicians.

4. WHAT IS THE PROCEDURE?

**What is the Acessa procedure?**
The Acessa procedure, also known as laparoscopic radiofrequency ablation (Lap. RFA), is preformed as an outpatient procedure (i.e., go home from the surgery the same-day) under general anesthesia (i.e., patients are asleep during surgery) to treat symptomatic uterine fibroids. It is a minimally invasive alternative to hysterectomy, myomectomy and uterine artery embolization (UAE) for uterine fibroids.\(^5\) Acessa utilizes radiofrequency ablation (heat) under laparoscopic ultrasound guidance to shrink the fibroid, without disrupting normal uterine tissue.\(^10\) The Acessa procedure allows the physician to treat almost all types of fibroids.\(^3,16\) See “How does the Acessa procedure work?” for more information on how the procedure works.
What should I expect the day of the Acessa procedure?

**Prep and Access** — You are prepped and brought into the operating room for anesthesia. Your physician makes two small incisions—one in your belly button, one below your bikini line and inserts a tiny camera and ultrasound into each incision. Using the instruments previously discussed, the surgeon treats each fibroid individually with radiofrequency energy (heat) that is specifically controlled to destroy the fibroid tissue with the goal of leaving the surrounding tissue unharmed.

**Visualize** - Your physician precisely locates each fibroid with the Acessa ultrasound probe and guidance mapping, allowing a full view of your uterus.

**Deploy** - Next, your physician deploys the tip of the Acessa handpiece into the fibroid while preserving healthy uterine tissue.

**Treat** - The physician deploys controlled heat through the Acessa handpiece to destroy the fibroid tissue. The physician repeats this process until every targeted fibroid is fully treated.

**Finish** - Once the procedure is complete, your physician stitches the small incisions on the skin. Ta da!

**Recover** - You will wake up in the recovery room. Most patients get cleared to go home within two hours. Women typically feel ready to return to work and daily activities after 4-5 days. In terms of when you will see symptom relief - It depends on how big the fibroid is and what symptoms you’re experiencing.

What makes Acessa, Acessa?

Our technology allows for a more thorough and less invasive method of treating your fibroids. Let’s dig into what makes Acessa different. The latest version of the technology (Acessa ProVu) is a fully integrated system with:

- **Ultrasound Probe** - This allows physicians to locate any and all fibroids you may have. Imagine X-ray vision for your uterus.

- **Acessa Handpiece** - This deploys controlled radiofrequency energy (heat) that destroys fibroid tissue. Imagine a light saber for fibroids.

- **Guidance Mapping** - This provides visual cues for physicians to ensure safe and thorough treatment. Imagine GPS for your car.

If the fibroids are not physically removed, how does Acessa work?

As a reminder, Acessa is a treatment for benign (non-cancerous) symptomatic fibroids. If patients are at risk for cancer, or malignancy, Acessa is not the appropriate treatment.

Studies show that fibroids do not have to be completely removed to resolve symptoms.\(^1,8\) Treating the fibroid cells so they shrink and stop putting pressure on the uterus may help to resolve symptoms. The data in the IDE clinical study showed even a 45.1% average shrinkage in fibroid volume can result in significant improvement in heavy periods, pelvic pain and bulk.\(^1\)
To summarize, Acessa works by heating the fibroid cells from the inside out, not by removing the fibroid. Cell tissues die when they reach a certain temperature. Acessa is designed to heat the fibroid tissue to the point that the tissue dies. The dead fibroid tissue shrinks and shrivels over time. The dead fibroid tissue is not harmful. It gets absorbed by the body, just like any dead tissue cell.³

What happens to the fibroid? How much do they shrink?

Once the fibroid is treated, the destroyed fibroid tissue shrinks over time. Total volume shrinkage is dependent on fibroid size and location. From the pivotal trial across 135 patients, there was an average of 45.1% decrease in fibroid volume at 12 months after the procedure.¹ Fibroids may continue to shrink after 12 months; however, results vary.¹

What does laparoscopic mean?

Laparoscopic surgery is a minimally invasive surgical technique where surgical tools are operated through small keyholes in the body and a camera (laparoscope) is used to see inside the body. Laparoscopic means there are only small incisions compared to an open procedure where the surgeon cuts a longer incisions.

Am I asleep during the Acessa procedure?

Yes, the procedure is performed under general anesthesia. Patients are not awake during the procedure. The procedure cannot be performed under local anesthesia.³

Can the Acessa procedure be performed in the office?

No, the procedure cannot be performed under local anesthesia nor in an office setting. Most office procedures do not have the ability to visualize and treat a wide variety of size, location and number of fibroids. Acessa can be performed at an Ambulatory Surgery Center or a hospital.

How long does the Acessa procedure take?

Each procedure varies in length based on the number and size of fibroids. Typically, the entire procedure from anesthesia to waking up lasts 1-2 hours.⁷ It may take longer for more fibroids or complications. Results may vary.

Is the Acessa procedure painful?

Patients may experience cramping or pelvic pain following the procedure. Typically, patients go home on a NSAIDs such as Tylenol and are able to return to normal activity in 4-5 days.⁶ Results may vary. Patients should discuss the Acessa procedure including its risks and benefits with their physician.
5. WHAT INFORMATION IS AVAILABLE ABOUT THE PROCEDURE?

How safe is the Acessa procedure? Is it clinically proven?

Radiofrequency ablation has been used for decades. The idea for laparoscopic radiofrequency ablation (Lap RFA) to treat fibroids, or the Acessa procedure, was first conceived by Dr. Bruce Lee in 1999. The original Acessa System was FDA cleared in November 2012. Since 2012, physicians have performed over 3,500 procedures with over 48 publications. The newest, most advanced technology, the Acessa ProVu system, was cleared in 2018.

“Our analysis indicates that Lap RFA is associated with low complication rates, minimal EBL, and low reintervention rates. In addition, patients reported major improvement in their HRQL and symptom severity scores compared to reports of more traditional interventions, such as hysterectomy, myomectomy, and UAE.”

– Havryliuk Meta Analysis JSLS 2017

What is the difference between Uterine Artery Embolization (UAE) vs Acessa?

UAE involves ischemic necrosis which consists of the tissue slowly dying due to lack of blood supply and typically involves an overnight stay for pain management. Acessa uses coagulative necrosis which destroys the fibroid cells and nerve endings with heat right away and results in the reduction of the fibroid volume over time.

UAE is performed by interventional radiologists. The Acessa procedure is performed by minimally invasive gynecologic surgeons.

What is the difference between Myomectomy vs Acessa?

Myomectomy involves cutting fibroids and removing the fibroid tissues from the uterus. Acessa, by comparison, does not require cutting or suturing within the uterus. Myomectomy is often considered a minimally invasive surgery because the incisions into the abdomen can be small. Acessa may be a less invasive option because there are zero incisions on the uterine surface (serosa) that require suturing, and only 2 to 3 small incision on the skin (myomectomy has 4 to 6 incisions in the skin).

6. WHAT ARE THE TYPICAL RESULTS?

What are typical results from the Acessa procedure?

The results of the Overall Treatment Effect Survey of the Pivotal study of 124 patients showed that 94% of the subjects responded that they were very satisfied, moderately satisfied, or somewhat satisfied with the treatment. At 12-months post-treatment, 98% of the subjects reported that they would probably or definitely recommend the procedure to their friends with the same health problem. When asked about the effectiveness of the treatment, at least 94% of the subjects responded that the treatment had been somewhat, moderately, or very effective in eliminating their symptoms.

Most patients report they have significantly lighter periods and alleviated pelvic pain and pressure. Often patients who experience “bulking” – looking pregnant/distended abdomen from the fibroids, report reduced or eliminated bulk symptoms. However, results may vary. To hear directly from patients, search “Acessa” on YouTube. Or check out our video section on www.accessaprocedure.com
7. WHY HAVEN’T I HEARD ABOUT ACESSA BEFORE? WHERE CAN I GET THE PROCEDURE?

How long has this option been available, why has my doctor never heard of the Acessa procedure?

Radiofrequency ablation has been used for decades. The idea for laparoscopic radiofrequency ablation (Lap RFA) to treat fibroids, or the Acessa procedure, was first conceived by Dr. Bruce Lee in 1999.2 The original Acessa System was FDA cleared in November 2012. Since 2012, physicians have performed over 3,500 procedures with over 48 publications.5 The newest, most advanced technology, the Acessa ProVu system, was cleared in 2018.

We are on a mission to give women more options. Thankfully, more and more physicians are learning about the Acessa procedure, and we are growing daily.

Where is the Acessa procedure offered in the US?

Minimally invasive gynecologic surgeons across the United States offer the procedure. We encourage you to call their offices, mention you found them through the Acessa website and make an appointment. See the list of surgeons who offer Acessa here www.acessaprocedure.com

Is the Acessa procedure offered outside the US?

The Acessa procedure is not currently offered outside of the US. However, there is a clinical study ongoing in Germany. Find out more at clinicaltrials.gov https://clinicaltrials.gov/ct2/show/NCT03028610

I’m from Canada, is there a waitlist I can get added to?

The Acessa Procedure for symptomatic fibroids is not offered in Canada at this time. Acessa Health intends to submit necessary regulatory required data to be evaluated by Health Canada in the near future.

Are there clinical studies I can join?

The studies that continue to enroll using Acessa Technology are:

- United States - https://clinicaltrials.gov/ct2/show/NCT02100904
- Germany - https://clinicaltrials.gov/ct2/show/NCT03028610

You should discuss whether you may be eligible for enrollment with your physician.

There are no physicians in my area who offer the Acessa procedure, what should I do?

Acessa is expanding daily. Many women travel for the procedure. Some physicians are accustomed to working with patients who are traveling. If you are interested in traveling for the procedure, we recommend reaching out to any Acessa trained physician’s office to learn more about their policies and your insurance coverage in that city or call the patient hotline at 800-992-4359.

When will patients feel symptom relief after the Acessa procedure?

The Acessa procedure is able to resolve many of the common fibroid symptoms including: extreme periods, stomach swelling and bloating, leg and back pain, stomach and pelvic pain, digestive issues, anemia, pain during sex, frequent urination.1 Based on our clinical data, the average reduction in menstrual blood loss was 87 mL less blood than baseline periods after 3 months and reduced even further to 103.6 mL less by 6 months.1 Most patients see the greatest effects 3—6 months after Acessa.1, 6 However, results may vary.

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Most patients choose to see another physician who offers Acessa for their surgery, and then they return to their original OBGYN for ongoing care. If your doctor has never heard of the Acessa procedure for fibroids, we encourage you to tell them about the procedure. We would be happy to train your physician if they have proper training in minimally invasive surgery. However, please note that not all OBGYN physicians are trained in minimally invasive surgery. Thus, not all OBGYN’s will be able to offer the Acessa procedure. If your physician is interested in being trained on the procedure, please have him or her reach out to Acessa Health at info@acessahealth.com.

Can my current physician do the Acessa procedure even if he or she is not on your list?
Acessa Health encourages patients to seek medical attention for typical and atypical symptoms associated with fibroids to help achieve and maintain good health with as high a quality of life as possible. Although many patients may benefit from the Acessa Procedure, this treatment is not for everyone and results may vary. You should talk to your doctor about the potential benefits and risks and whether this treatment is right for you. Information contained on this site is not to be used as a substitute for talking to your doctor. You should always talk to your doctor about the benefits and risks and whether this treatment is right for you. Rx Only.

Legal Disclaimer:
Acessa ProVu System is cleared by the FDA for the treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. The Acessa procedure is generally safe but complications may occur and can be serious. Risks and complications associated with the Acessa procedure include, but are not limited to: skin burns from the dispersion of radiofrequency energy, mild intra-operative bleeding, transient urinary retention or urinary tract infection, adhesion formation, post-procedural discomfort (cramping, pelvic pain), and transient amenorrhea, infection, injury to adjacent structures, vaginal bleeding and temporary anemia, blood loss requiring transfusion or hysterectomy, pneumothorax, wound dehiscence, deep vein thrombosis and pulmonary embolus, treatment failure, and complications related to laparoscopy and/or general anesthesia including death. Insufficient data exist on which to evaluate the safety and effectiveness of Acessa procedure in women who plan future pregnancy. Therefore, the Acessa procedure is not recommended for women who are planning future pregnancy. There is limited data regarding pregnancy following the Acessa procedure, if you become pregnant following the Acessa procedure, you should contact your doctor immediately. Please consult with your doctor to understand the risks and benefits of surgery and find out if Acessa may be right for you. Rx Only.

Reimbursement Disclaimer:
Reimbursement information is provided for convenience only and is not legal advice or official guidance from payers. It is not intended to increase or maximize reimbursement by any payor. Hospitals and physicians are solely responsible for being in compliance with Medicare and other payer rules and requirements for the information submitted with all claims and appeals. Acessa Health, Inc. does not warrant or guarantee that the use of this information will result in coverage or payment. Before any claims or appeals are submitted, hospitals and physicians should review official payor instructions and requirements, should confirm the accuracy of their coding or billing practices with these payors and should use independent judgment when selecting codes that most appropriately describe the services or supplies provided to a patient. CPT five-digit numeric codes, descriptions, and numeric modifiers are © 2020 AMA. All rights reserved.

Risk Statement:
The Acessa ProVu System is cleared by the FDA for the treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. The Acessa procedure is generally safe but complications may occur and can be serious. Risks and complications associated with the Acessa procedure include, but are not limited to: skin burns from the dispersion of radiofrequency energy, mild intra-operative bleeding, transient urinary retention or urinary tract infection, adhesion formation, post-procedural discomfort (cramping, pelvic pain), and transient amenorrhea, infection, injury to adjacent structures, vaginal bleeding and temporary anemia, blood loss requiring transfusion or hysterectomy, pneumothorax, wound dehiscence, deep vein thrombosis and pulmonary embolus, treatment failure, and complications related to laparoscopy and/or general anesthesia including death. Insufficient data exist on which to evaluate the safety and effectiveness of Acessa procedure in women who plan future pregnancy. Therefore, the Acessa procedure is not recommended for women who are planning future pregnancy. There is limited data regarding pregnancy following the Acessa procedure, if you become pregnant following the Acessa procedure, you should contact your doctor immediately. Please consult with your doctor to understand the risks and benefits of surgery and find out if Acessa may be right for you. Rx Only.

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