# Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids

**Policy #** 00445
Original Effective Date: 09/17/2014
Current Effective Date: 09/13/2021

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Occlusion of Uterine Arteries Using Transcatheter Embolization or Laparoscopic Occlusion to Treat Uterine Fibroids is addressed separately in medical policy 00130.*

*Note: Magnetic Resonance-Guided Focused Ultrasound is addressed separately in medical policy 00180.*

## When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider ultrasound-guided radiofrequency ablation (e.g., Acessa™, Sonata®)‡ for the treatment of uterine fibroids to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility may be considered for ultrasound-guided radiofrequency ablation (e.g., Acessa™, Sonata®)‡ for the treatment of uterine fibroids when **ANY** the following conditions are met:

- Excessive uterine bleeding as evidenced by either profuse bleeding lasting more than eight days, or anemia due to acute or chronic blood loss; or
- Pelvic discomfort caused by leiomyomata, manifested as:
  - Acute severe pain; OR
  - Chronic lower abdominal pain; OR
  - Low back pressure; OR
  - Bladder pressure with urinary frequency not due to urinary tract infection.

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# When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers all other techniques of myolysis as a treatment of uterine fibroids not noted above to be **investigational***, including Nd:Yag Lasers, bipolar electrodes, and supercooled cryoprobes.

The use of ultrasound-guided radiofrequency ablation (e.g., Acessa™, Sonata®)‡ for the treatment of uterine fibroids when patient selection criteria are not met is considered to be **investigational.***

# Policy Guidelines

In November 2014, the U.S. Food and Drug Administration published a safety communication on laparoscopic power morcellators used for myomectomy and hysterectomy in most women. (Morcellators are not otherwise addressed herein). The Administration recommended that manufacturers of these devices include in their product labels a boxed safety warning and wording on contraindications
(see
https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM424123.pdf).

# Background/Overview

**Uterine Fibroids**

Uterine fibroids, also known as leiomyomas, are among the most common conditions affecting women in their reproductive years; symptoms include menorrhagia, pelvic pressure, or pain.

**Treatment**

Surgery, including hysterectomy and various myomectomy procedures, is considered the criterion standard for symptom resolution. However, there is the potential for surgical complications and, in the case of a hysterectomy, the uterus is not preserved. In addition, multiple myomectomies may be associated with longer operating time, postoperative febrile morbidity, and development of pelvic adhesions. There has been long-standing research interest in developing minimally invasive

alternatives for treating uterine fibroids, including procedures that retain the uterus and permit future childbearing. Treatment options include uterine artery embolization (see medical policy 00130) and the transcutaneous magnetic resonance imaging-guided focused ultrasound therapy (see medical policy 00180). Various techniques to induce myolysis have also been studied including Nd:YAG lasers, bipolar electrodes, cryomyolysis, and radiofrequency ablation. With these techniques, an energy source is used to create areas of necrosis within uterine fibroids, reducing their volume and thus relieving symptoms. Early methods involved multiple insertions of probes into the fibroid, performed without imaging guidance. There were concerns about serosal injury and abdominopelvic adhesions with these techniques, possibly due to the multiple passes through the serosa needed to treat a single fibroid. Newer systems using radiofrequency energy do not require repetitive insertions of needle electrodes. Ultrasonography is used laparoscopically or transcervically to determine the size and location of fibroids, to guide the probe, and to ensure the probe is in the correct location so that optimal energy is applied to the fibroid. Percutaneous approaches using magnetic resonance imaging guidance have also been reported.

# FDA or Other Governmental Regulatory Approval

**U.S. Food and Drug Administration (FDA)**

In 2012, the Acessa™‡ System (Acessa Health, formerly Halt Medical) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for percutaneous laparoscopic coagulation and ablation of soft tissue and treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance (K121858). The technology was previously approved in 2010, at which time it was called the Halt 2000GI™‡ Electrosurgical Radiofrequency Ablation System. In 2014, the ultrasound guidance system received marketing clearance from the FDA (K132744). FDA product code: GEI. In 2018, the third-generation Acessa™‡ ProVu System®‡ was cleared for marketing by the FDA through the 510(k) process for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. (K181124). FDA product code: HFG.

In 2018, the Sonata®‡ Sonography-Guided Transcervical Fibroid Ablation System (Gynsonics) was cleared for marketing by the FDA through the 510(k) process for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids (K173703). The Sonata system was previously known as Vizablate. FDA product codes: KNF, ITX, and IYO.

Cryoablation is a surgical procedure that uses previously approved and available cryoablation systems; and as a surgical procedure, it is not subject to regulation by the FDA. Other products addressed in this review (eg,Nd:YAG lasers, bipolar electrodes) have long-standing FDA approval, and there are no products specifically approved for the treatment of uterine fibroids.

# Rationale/Source

**Description**

Various minimally invasive treatments for uterine fibroids have been proposed as alternatives to surgery. Among these approaches are laparoscopic and percutaneous techniques to induce myolysis, which includes radiofrequency ablation (RFA), laser and bipolar needles, cryomyolysis, and magnetic resonance imaging-guided laser ablation.

**Summary of Evidence**

For individuals who have symptomatic uterine fibroids who receive RFA, the evidence includes prospective cohorts, an RCT and systematic review. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The meta-analysis found low rates of reintervention with RFA and quality of life outcomes that were similar to uterine artery embolization and myomectomy at 12 months. Data on reintervention rates at 36 months were limited to 1 study and no studies reported reintervention rates at 60 months. The single RCT with a follow-up longer than 3 months found that RFA was noninferior to laparoscopic myomectomy on the trial's primary outcome: length of hospitalization. A number of secondary outcomes were reported at 12 and 24 months, including symptoms and quality of life. None of the secondary outcomes demonstrated significant between-group differences in a subgroup analysis of 43 patients. The procedure has faster recovery than myomectomy, and provides a reduction in symptoms and improvement in quality of life in the short term. Recurrence and reintervention rates at longer follow-up are unknown.

For individuals who have symptomatic uterine fibroids who receive laser or bipolar needles, the evidence includes case series. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The case series were published in the 1990s, and the procedures used then may not reflect current practice. RCTs comparing laser or bipolar needles with alternative treatments for uterine fibroids are needed to evaluate the safety and efficacy of this technology adequately. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have symptomatic uterine fibroids who receive cryomyolysis, the evidence includes case series. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. Among the few case series, sample sizes were small (≤20 patients). RCTs comparing cryomyolysis with alternative treatments for uterine fibroids are needed to evaluate the safety and efficacy of this technology adequately. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have symptomatic uterine fibroids who receive magnetic resonance imaging-guided laser ablation, the evidence includes a study with historical controls. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. A single study with historical controls is not sufficiently robust to evaluate this technology. RCTs comparing magnetic resonance imaging-guided laser ablation with alternative treatments for uterine fibroids are needed to evaluate safety and efficacy adequately. The evidence is insufficient to determine the effects of the technology on health outcomes.

# Supplemental Information

## Practice Guidelines and Position Statements

### American College of Obstetricians and Gynecologists

In 2021, the American College of Obstetricians and Gynecologists published Practice Bulletin on Symptomatic Uterine Leiomyomas and noted that laparoscopic radiofrequency ablation (RFA) can be considered as a minimally invasive treatment option for the management of symptomatic leiomyomas in patients who desire uterine preservation and are counseled about the limited available data on reproductive outcomes (Level B recommendation based on limited or inconsistent scientific evidence). "Although laparoscopic RFA with a leiomyoma-specific FDA- approved device has been studied primarily in nonrandomized trials, 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, which included over 1,800 patients, 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." It was also noted that complication reporting was highly inconsistent, but no serious procedural complications such as death or injury to visceral structures was reported in any of the included studies.

In 2019, the American College of Obstetricians and Gynecologists reaffirmed its 2008 position on alternatives to hysterectomy in the management of leiomyomas. Recommendations based on good and consistent scientific evidence were that abdominal myomectomy is a safe and effective treatment for women with symptomatic leiomyomas and that uterine artery embolization is a safe and effective option for appropriately selected women who want to retain their uteri. The bulletin contained no recommendations on myolysis using laparoscopic or percutaneous techniques.

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**
Some currently ongoing and unpublished trials that might influence this evidence review are listed in Table 1.

**Table 1. Summary of Key Trials**

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| ***Ongoing*** | | | |
| NCT02260752 | Patient-Centered Results for Uterine Fibroids (COMPARE-UF) | 3,094 | Sep 2020 published |
| NCT01563783[a] | The Trust (Treatment Results of Uterine Sparing Technologies) Study | 260 | Jun 2022 |
| NCT03219385 | Directed Ablation of Uterine Fibroids Using a Noninvasive Approach (DIANA) | 180 | Sep 2022 |
| NCT03118037 | Transcervical Radiofrequency Ablation of Uterine Fibroids Global Registry (SAGE) | 100 | Dec 2023 |

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|---|---|---|---|
| NCT02163525[a] | Post Market TRUST - U.S.A. Study | 114 | Jun 2024 |
| NCT02100904 | Uterine Leiomyoma Treatment With Radiofrequency Ablation (ULTRA) Registry (ULTRA Registry) | 400 | Jan 2025 |
| ***Unpublished*** | | | |
| NCT01750008[a] | The LUSTOR (Laparoscopic Uterine Sparing Techniques Outcomes and Reinterventions)Trial | 51 | Jun 2018 |

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

# References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids", 4.01.19, September 2020.
2. Jones S, O'Donovan P, Toub D. Radiofrequency ablation for treatment of symptomatic uterine fibroids. Obstet Gynecol Int. 2012; 2012: 194839. PMID 21961009
3. Davis MR, Soliman AM, Castelli-Haley J, et al. Reintervention Rates After Myomectomy, Endometrial Ablation, and Uterine Artery Embolization for Patients with Uterine Fibroids. J Womens Health (Larchmt). Oct 2018; 27(10): 1204-1214. PMID 30085898
4. Sandberg EM, Tummers FHMP, Cohen SL, et al. Reintervention risk and quality of life outcomes after uterine-sparing interventions for fibroids: a systematic review and meta-analysis. Fertil Steril. Apr 2018; 109(4): 698-707.e1. PMID 29653718
5. Havryliuk Y, Setton R, Carlow JJ, et al. Symptomatic Fibroid Management: Systematic Review of the Literature. JSLS. Jul-Sep 2017; 21(3). PMID 28951653
6. Lin L, Ma H, Wang J, et al. Quality of Life, Adverse Events, and Reintervention Outcomes after Laparoscopic Radiofrequency Ablation for Symptomatic Uterine Fibroids: A Meta-Analysis. J Minim Invasive Gynecol. Mar 2019; 26(3): 409-416. PMID 30253997
7. Bradley LD, Pasic RP, Miller LE. Clinical Performance of Radiofrequency Ablation for Treatment of Uterine Fibroids: Systematic Review and Meta-Analysis of Prospective Studies. J Laparoendosc Adv Surg Tech A. Dec 2019; 29(12): 1507-1517. PMID 31702440

8. Brucker SY, Hahn M, Kraemer D, et al. Laparoscopic radiofrequency volumetric thermal ablation of fibroids versus laparoscopic myomectomy. Int J Gynaecol Obstet. Jun 2014; 125(3): 261-5. PMID 24698202
9. Hahn M, Brucker S, Kraemer D, et al. Radiofrequency Volumetric Thermal Ablation of Fibroids and Laparoscopic Myomectomy: Long-Term Follow-up From a Randomized Trial. Geburtshilfe Frauenheilkd. May 2015; 75(5): 442-449. PMID 26097247
10. Kramer B, Hahn M, Taran FA, et al. Interim analysis of a randomized controlled trial comparing laparoscopic radiofrequency volumetric thermal ablation of uterine fibroids with laparoscopic myomectomy. Int J Gynaecol Obstet. May 2016; 133(2): 206-11. PMID 26892690
11. Miller CE, Osman KM. Transcervical Radiofrequency Ablation of Symptomatic Uterine Fibroids: 2-Year Results of the SONATA Pivotal Trial. J Gynecol Surg. Dec 01 2019; 35(6): 345-349. PMID 32226268
12. Brolmann H, Bongers M, Garza-Leal JG, et al. The FAST-EU trial: 12-month clinical outcomes of women after intrauterine sonography-guided transcervical radiofrequency ablation of uterine fibroids. Gynecol Surg. NA 2016; 13: 27-35. PMID 26918001
13. Keltz J, Levie M, Chudnoff S. Pregnancy Outcomes After Direct Uterine Myoma Thermal Ablation: Review of the Literature. J Minim Invasive Gynecol. May 2017; 24(4): 538-545. PMID 28109894
14. Goldfarb HA. Bipolar laparoscopic needles for myoma coagulation. J Am Assoc Gynecol Laparosc. Feb 1995; 2(2): 175-9. PMID 9050553
15. Goldfarb HA. Nd:YAG laser laparoscopic coagulation of symptomatic myomas. J Reprod Med. Jul 1992; 37(7): 636-8. PMID 1387912
16. Nisolle M, Smets M, Malvaux V, et al. Laparoscopic myolysis with the Nd:YAG laser. J Gynecol Surg. 1993; 9(2): 95-9. PMID 10171973
17. Donnez J, Squifflet J, Polet R, et al. Laparoscopic myolysis. Hum Reprod Update. Nov-Dec 2000; 6(6): 609-13. PMID 11129695
18. Phillips DR, Nathanson HG, Milim SJ, et al. Laparoscopic Leiomyoma Coagulation. J Am Assoc Gynecol Laparosc. Aug 1996; 3(4, Supplement): S39. PMID 9074213
19. Zreik TG, Rutherford TJ, Palter SF, et al. Cryomyolysis, a new procedure for the conservative treatment of uterine fibroids. J Am Assoc Gynecol Laparosc. Feb 1998; 5(1): 33-8. PMID 9454874
20. Zupi E, Piredda A, Marconi D, et al. Directed laparoscopic cryomyolysis: a possible alternative to myomectomy and/or hysterectomy for symptomatic leiomyomas. Am J Obstet Gynecol. Mar 2004; 190(3): 639-43. PMID 15041993

21. Zupi E, Marconi D, Sbracia M, et al. Directed laparoscopic cryomyolysis for symptomatic leiomyomata: one-year follow up. J Minim Invasive Gynecol. Jul-Aug 2005; 12(4): 343-6. PMID 16036195
22. Hindley JT, Law PA, Hickey M, et al. Clinical outcomes following percutaneous magnetic resonance image guided laser ablation of symptomatic uterine fibroids. Hum Reprod. Oct 2002; 17(10): 2737-41. PMID 12351555
23. American College of Obstetricians and Gynecologists. ACOG practice bulletin. Management of Symptomatic Uterine Leiomyomas. Obstet Gynecol. June 2021; 137 (6): 100-115.
24. American College of Obstetricians and Gynecologists. ACOG practice bulletin. Alternatives to hysterectomy in the management of leiomyomas. Obstet Gynecol. Aug 2008; 112(2 Pt 1): 387-400. PMID 18669742

# Policy History

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|---|---|
| 09/04/2014 | Medical Policy Committee review |
| 09/17/2014 | Medical Policy Implementation Committee approval. New policy. |
| 08/03/2015 | Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed. |
| 09/03/2015 | Medical Policy Committee review |
| 09/23/2015 | Medical Policy Implementation Committee approval. No change to coverage. |
| 01/01/2016 | Coding update |
| 09/08/2016 | Medical Policy Committee review |
| 09/21/2016 | Medical Policy Implementation Committee approval. No change to coverage. |
| 01/01/2017 | Coding update: Removing ICD-9 Diagnosis Codes and CPT coding update |
| 10/05/2017 | Medical Policy Committee review |
| 10/18/2017 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 10/04/2018 | Medical Policy Committee review |
| 10/17/2018 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 10/03/2019 | Medical Policy Committee review |

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| 10/09/2019 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 10/01/2020 | Medical Policy Committee review |
| 10/07/2020 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 08/05/2021 | Medical Policy Committee review |
| 08/11/2021 | Medical Policy Implementation Committee approval. Replaced the investigational statement with an eligible for coverage with criteria statement for ultrasound-guided radiofrequency ablation for the treatment of uterine fibroids. Added an investigational statement for all other techniques of myolysis as a treatment of uterine fibroids. |

Next Scheduled Review Date: 08/2022

# Coding

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

| Code Type | Code |
|---|---|
| CPT | 0404T, 58578, 58674, 58999, 76940, 77022 |
| HCPCS | No codes |
| ICD-10 Diagnosis | D25.0-D25.9 |

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.