



Louisiana

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

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 laparoscopic or transcervical radiofrequency ablation (RFA) as a treatment of symptomatic uterine fibroids in individuals 18 years and older to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility may be considered for laparoscopic or transcervical radiofrequency ablation (RFA) as a treatment of symptomatic uterine fibroids in individuals 18 years and older when **ALL** of the following conditions are met:

- Evidence of uterine fibroids via ultrasound that are less than 10 cm in diameter for laparoscopic RFA with Acessa or 7 cm for transcervical RFA with Sonata; **AND**
- Patient desires a uterine-sparing treatment approach or is ineligible for hysterectomy or other uterine-sparing alternatives to RFA (e.g., laparoscopic myomectomy, uterine artery embolization [UAE]) (see Policy Guidelines); **AND**

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

- Patient has experienced at least 1 of the following symptoms that are a direct result of the fibroid(s):
 - Menorrhagia or other abnormal uterine bleeding that interferes with daily activities or causes anemia (see Policy Guidelines);
 - Pelvic pain or pressure;
 - Urinary symptoms (e.g., urinary frequency, urgency) related to bulk compression of the bladder;
 - Gastrointestinal symptoms related to bulk compression of the bowel (e.g., constipation, bloating);
 - Dyspareunia (painful or difficult sexual relations).

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 other laparoscopic, transcervical, or percutaneous techniques for myolysis of uterine fibroids, including use of laser or bipolar needles, cryomyolysis, and magnetic resonance imaging-guided laser ablation to be **investigational***

The use of laparoscopic or transcervical radiofrequency ablation (RFA) as a treatment of symptomatic uterine fibroids in individuals 18 years and older when patient selection criteria are not met is considered to be **investigational.***

Policy Guidelines

Eligibility Considerations

Abnormal uterine bleeding refers to uterine bleeding of abnormal frequency, duration, and volume that interferes with a patient's quality of life. Patients with abnormal uterine bleeding with an inadequate response to appropriately selected medical therapy may be considered for alternate uterine-sparing interventions. In patients >45 years of age with menorrhagia or other abnormal bleeding, endometrial biopsy is recommended prior to treatment to rule out endometrial malignancy and/or additional assessment to rule out a risk for uterine leiomyosarcoma.

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

Clinical trial experience with radiofrequency ablation (RFA) has been limited to patients with overall uterine size ≤ 16 gestational weeks size based on pelvic examination. In patients where fibroids cannot be distinguished from adenomyosis on ultrasound, advanced imaging (e.g., magnetic resonance imaging [MRI]) may be required. For patients with pelvic pain, alternative causes such as endometritis and active pelvic inflammatory disease should be excluded prior to treatment with RFA.

Treatment Approach Considerations for Radiofrequency Ablation

Uterine fibroids are categorized according to the International Federation of Gynaecology and Obstetrics (FIGO) leiomyoma subclassification system (see Table PG1). Choice of laparoscopic versus transcervical RFA treatment is dependent on fibroid number, size, type and location, and patient preferences. For example, predominantly lower uterine segment or cervical leiomyomata, or those with a predominant submucosal location or intramural FIGO type 2 or 3 fibroids, may suggest a transcervical approach, whereas fibroids with largely fundal or extramural components may suggest a laparoscopic approach. Patients aiming to avoid future deliveries via obligate cesarean section may prefer a transcervical approach. Select women with numerous fibroids may benefit from combined laparoscopic RFA and laparoscopic myomectomy. Patients with intramural fibroids, intra-abdominal adhesions, or medical contraindications may not be candidates for alternative uterine-sparing interventions.

Table PG1. FIGO Leiomyoma Subclassification System

Group	Type	Description
Submucosal	0	Pedunculated intracavitary
	1	<50% intramural ($\geq 50\%$ submucosal)
	2	$\geq 50\%$ intramural (<50% submucosal)
Other	3	100% intramural, contacting endometrium
	4	100% intramural, no endometrial or subserosal contact
	5	Subserosal, $\geq 50\%$ intramural
	6	Subserosal, <50% intramural
	7	Pedunculated subserosal

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

	8	Non-myometrial location (eg, cervical, broad ligament, parasitic)
Hybrid	X-X	Both submucosal and subserosal components. Submucosal component designated by first number and subserosal component designated by second number.

FIGO: International Federation of Gynaecology and Obstetrics.

Table adapted from Gomez et al (2021). MRI-based pictorial review of the FIGO classification system for uterine fibroids. *Abdom Radiol.* 46(5): 2146-2155. PMID: 33385249.

Reinterventions

Reintervention with RFA may be considered for patients meeting policy criteria with documentation of new or recurrent fibroid development following a partial response with the initial procedure. However, data on reinterventions for new or recurrent fibroids is limited and documentation procedures for repeat anatomic mapping of fibroids are not standardized.

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. It is estimated that uterine fibroids occur in up to 70% of women by menopause, with approximately 25% of these being clinically significant and requiring intervention. The prevalence rate of uterine fibroids is 2-3 times higher among Black women compared with White women, and there are higher rates of hysterectomy and myomectomy compared with non-surgical therapy, potentially demonstrating a disparity in access to uterine-sparing interventions.

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

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

childbearing. Treatment options include uterine artery embolization and 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). Hologic acquired Accessa Health in 2020. FDA product code: HFG.

In 2018, the Sonata®‡ Sonography-Guided Transcervical Fibroid Ablation System (Gynesonics) was cleared for marketing by the FDA through the 510(k) process for diagnostic intrauterine imaging and transcervical radiofrequency ablation as treatment of symptomatic uterine fibroids (K173703). The Sonata System 2.1 received marketing clearance in 2020 (K193516) and the Sonata System 2.2

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

received marketing clearance in 2021 (K211535). 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

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Various minimally invasive treatments for uterine fibroids have been proposed as alternatives to surgery. Among these approaches are laparoscopic ,percutaneous, and transcervical 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, RCTs, and systematic reviews. 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 RCT and 1 cohort study with high loss to follow-up. No studies reported reintervention rates at 60 months. Two RCTs found that RFA was noninferior to laparoscopic myomectomy on the primary outcome: length of hospitalization. A number of secondary outcomes were reported at 12 and 24 months in 1 RCT, 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. Well-designed

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

comparative trials with longer follow-up are needed to determine the effect of RFA on health outcomes compared with other treatment options such as myomectomy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

Additional Information

2021 Input

Clinical input was sought to help determine whether the use of laparoscopic or RFA for individuals with symptomatic uterine fibroids would provide a clinically meaningful improvement in the net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input on the use of RFA was received from 3 respondents: 1 society-

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

level response including input from physicians affiliated with academic medical centers and 2 physician-level responses with academic affiliations.

For individuals with symptomatic uterine fibroids, clinical input provides consistent support that the use of laparoscopic or transcervical RFA provides a clinically meaningful improvement in the net health outcome and is consistent with generally accepted medical practice.

Based on the evidence and independent clinical input, the clinical input supports that the following indication provides a clinically meaningful improvement in the net health outcome and is consistent with generally accepted medical practice.

Women 18 and older when ALL of the following conditions are met:

- Evidence of uterine fibroids via ultrasound that are less than 10 cm in diameter for laparoscopic RFA with Acessa or 7 cm for transcervical RFA with Sonata; AND
- Patient desires a uterine-sparing treatment approach or is ineligible for hysterectomy or other uterine-sparing alternatives to RFA (e.g., laparoscopic myomectomy, uterine artery embolization [UAE]); AND
- Patient has experienced at least 1 of the following symptoms that are a direct result of the fibroid(s):
 - Menorrhagia or other abnormal uterine bleeding that interferes with daily activities or causes anemia;
 - Pelvic pain or pressure;
 - Urinary symptoms (e.g., urinary frequency, urgency) related to bulk compression of the bladder;
 - Gastrointestinal symptoms related to bulk compression of the bowel (e.g., constipation, bloating);
 - Dyspareunia (painful or difficult sexual relations).

Respondents noted that choice of laparoscopic versus transcervical RFA treatment is dependent on fibroid number, type and location, and patient preferences. For example, predominantly lower uterine segment or cervical leiomyomata, or those with a predominant submucosal location or intramural International Federation of Gynecology and Obstetrics (FIGO) type 2 or 3 fibroids (see Table PG1), may suggest a transcervical approach, whereas fibroids with largely fundal or extramural components may suggest a laparoscopic approach.

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2021 Input

Clinical input was sought to help determine whether the use of laparoscopic or transcervical radiofrequency ablation (RFA) for individuals with symptomatic uterine fibroids would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input on the use of RFA was received from 3 respondents, including: 1 society-level response including input from physicians affiliated with academic medical centers and 2 physician-level responses with academic affiliations. For individuals with symptomatic uterine fibroids, clinical input provides consistent support that the use of laparoscopic or transcervical RFA provides a clinically meaningful improvement in the net health outcome and is consistent with generally accepted medical practice.

Based on the evidence and independent clinical input, the clinical input supports that the following indication provides a clinically meaningful improvement in the net health outcome and is consistent with generally accepted medical practice.

Women 18 and older when ALL of the following conditions are met:

- Evidence of uterine fibroids via ultrasound that are less than 10 cm in diameter for laparoscopic RFA with Acessa or 7 cm for transcervical RFA with Sonata; AND
- Patient desires a uterine-sparing treatment approach or is contraindicated for hysterectomy or other uterine-sparing alternatives to RFA (e.g., laparoscopic myomectomy, uterine artery embolization [UAE]); AND
- Patient has experienced at least 1 of the following symptoms that are a direct result of the fibroid(s):
 - Menorrhagia or other abnormal uterine bleeding that interferes with daily activities or causes anemia;
 - Pelvic pain or pressure;

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

- Urinary symptoms (e.g., urinary frequency, urgency) related to bulk compression of the bladder;
- Gastrointestinal symptoms related to bulk compression of the bowel (e.g., constipation, bloating);
- Dyspareunia (painful or difficult sexual relations).

Respondents noted that choice of laparoscopic versus transcervical RFA treatment is dependent on fibroid number, type and location, and patient preferences. For example, predominantly lower uterine segment or cervical leiomyomata, or those with a predominant submucosal location or intramural International Federation of Gynecology and Obstetrics (FIGO) type 2 or 3 fibroids (see Table PG1), may suggest a transcervical approach, whereas fibroids with largely fundal or extramural components may suggest a laparoscopic approach.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Obstetricians and Gynecologists

In 2021, the American College of Obstetricians and Gynecologists updated its practice bulletin on the management of symptomatic leiomyomas.¹ Recommendations based on a review of evidence included the following:

- Radiofrequency ablation can be considered as a minimally invasive treatment option in patients who desire to retain their uterus, provided they are counseled about the limited data on reproductive outcomes. Laparoscopic, transvaginal, or transcervical approaches using ultrasound guidance are considered similarly effective.
- Focused ultrasound is associated with a reduction in leiomyoma and uterine size, but is associated with less improvement in symptoms and quality of life and a higher risk of reintervention compared with uterine artery embolization.
- Myomectomy was recommended as an option in patients who desire uterine preservation or future pregnancy and are counseled about the risk of recurrence. The laparoscopic approach

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

is associated with shorter hospitalization, less postoperative pain, faster return to work, and earlier return to normal activities.

- Hysterectomy is recommended as a definitive surgical management option in patients who do not desire future childbearing or do not wish to retain their uterus.

National Institute for Health and Care Excellence

In 2021, the National Institute for Health and Care Excellence (NICE) published an interventional procedures guidance on the use of transcervical ultrasound-guided radiofrequency ablation (RFA) for symptomatic uterine fibroids.³³ The NICE noted that while evidence on the safety of transcervical RFA raises no major safety concerns, evidence on the efficacy of the procedure is limited in quality. Therefore, the NICE recommends that the procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

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
<i>Ongoing</i>			
NCT01563783 ^a	The Trust (Treatment Results of Uterine Sparing Technologies) Study	260	Sep 2022
NCT03219385 ^a	Directed Ablation of Uterine Fibroids Using a Noninvasive Approach (DIANA)	180	Sep 2022

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

NCT03118037 ^a	Transcervical Radiofrequency Ablation of Uterine Fibroids Global Registry (SAGE)	100	Dec 2025
NCT02163525 ^a	Post Market TRUST - U.S.A. Study	114	Jun 2024
NCT02100904	Uterine Leiomyoma Treatment With Radiofrequency Ablation (ULTRA) Registry (ULTRA Registry)	800	Jan 2025
<i>Unpublished</i>			
NCT02260752	Patient-Centered Results for Uterine Fibroids (COMPARE-UF)	3,094	Sep 2020

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

References

1. Stewart MR, Adelman VL, Jacoby MR. Management of Symptomatic Uterine Leiomyomas: ACOG Practice Bulletin, Number 228. *Obstet Gynecol.* Jun 01 2021; 137(6): e100-e115. PMID 34011888
2. Laughlin-Tommaso SK, Jacoby VL, Myers ER. Disparities in Fibroid Incidence, Prognosis, and Management. *Obstet Gynecol Clin North Am.* Mar 2017; 44(1): 81-94. PMID 28160895
3. Stewart EA, Nicholson WK, Bradley L, et al. The burden of uterine fibroids for African-American women: results of a national survey. *J Womens Health (Larchmt).* Oct 2013; 22(10): 807-16. PMID 24033092
4. Jones S, O'Donovan P, Toub D. Radiofrequency ablation for treatment of symptomatic uterine fibroids. *Obstet Gynecol Int.* 2012; 2012: 194839. PMID 21961009
5. 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
6. 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
7. Havryliuk Y, Setton R, Carlow JJ, et al. Symptomatic Fibroid Management: Systematic Review of the Literature. *JSL.* Jul-Sep 2017; 21(3). PMID 28951653

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

8. 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
9. 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
10. Arnreiter C, Oppelt P. A Systematic Review of the Treatment of Uterine Myomas Using Transcervical Ultrasound-Guided Radiofrequency Ablation with the Sonata System. *J Minim Invasive Gynecol.* Aug 2021; 28(8): 1462-1469. PMID 33892184
11. 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
12. Rattray DD, Weins L, Regush LC, et al. Clinical outcomes and health care utilization pre- and post-laparoscopic radiofrequency ablation of symptomatic fibroids and laparoscopic myomectomy: a randomized trial of uterine-sparing techniques (TRUST) in Canada. *Clinicoecon Outcomes Res.* 2018; 10: 201-212. PMID 29670382
13. Yu S, Silverberg K, Bhagavath B, et al. Post-Market Safety of Laparoscopic Ultrasound-Guided Radiofrequency Ablation. *JLS.* Oct-Dec 2020; 24(4). PMID 33510567
14. 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
15. 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
16. Jacoby VL, Parvataneni R, Oberman E, et al. Laparoscopic Radiofrequency Ablation of Uterine Leiomyomas: Clinical Outcomes during Early Adoption into Surgical Practice. *J Minim Invasive Gynecol.* May 2020; 27(4): 915-925. PMID 31376584
17. 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
18. Lukes A, Green MA. Three-Year Results of the SONATA Pivotal Trial of Transcervical Fibroid Ablation for Symptomatic Uterine Myomata. *J Gynecol Surg.* Oct 01 2020; 36(5): 228-233. PMID 33061253

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

19. 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
20. Shifrin G, Engelhardt M, Gee P, et al. Transcervical fibroid ablation with the Sonata system for treatment of submucous and large uterine fibroids. *Int J Gynaecol Obstet.* Oct 2021; 155(1): 79-85. PMID 33544889
21. Christoffel L, Romer T, Schiermeier S. Transcervical Radiofrequency Ablation of Uterine Fibroids Global Registry (SAGE): Study Protocol and Preliminary Results. *Med Devices (Auckl).* 2021; 14: 77-84. PMID 33688276
22. 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
23. Berman JM, Shashoua A, Olson C, et al. Case Series of Reproductive Outcomes after Laparoscopic Radiofrequency Ablation of Symptomatic Myomas. *J Minim Invasive Gynecol.* Mar 2020; 27(3): 639-645. PMID 31238151
24. Goldfarb HA. Bipolar laparoscopic needles for myoma coagulation. *J Am Assoc Gynecol Laparosc.* Feb 1995; 2(2): 175-9. PMID 9050553
25. Goldfarb HA. Nd:YAG laser laparoscopic coagulation of symptomatic myomas. *J Reprod Med.* Jul 1992; 37(7): 636-8. PMID 1387912
26. 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
27. Donnez J, Squifflet J, Polet R, et al. Laparoscopic myolysis. *Hum Reprod Update.* Nov-Dec 2000; 6(6): 609-13. PMID 11129695
28. Phillips DR, Nathanson HG, Milim SJ, et al. Laparoscopic Leiomyoma Coagulation. *J Am Assoc Gynecol Laparosc.* Aug 1996; 3(4, Supplement): S39. PMID 9074213
29. 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
30. 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
31. 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

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

- 32. 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
- 33. National Institute for Health and Care Excellence (NICE). Interventional procedures guidance: Transcervical ultrasound-guided radiofrequency ablation for symptomatic uterine fibroids [IPG689]. March 31, 2021; <https://www.nice.org.uk/guidance/ipg689>.

Policy History

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

- 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
- 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

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

- 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.
- 08/04/2022 Medical Policy Committee review
- 08/10/2022 Medical Policy Implementation Committee approval. Title changed from “Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids“ to “Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis“. Revised the entire coverage section.

Next Scheduled Review Date: 08/2023

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 2021 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.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

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 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

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/01/2022

- 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.

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.