



MASSACHUSETTS

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## Medical Policy

# Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroids Myolysis

### Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)

### Policy Number: 244

BCBSA Reference Number: 4.01.19 (For Plan internal use only)

NCD/LCD: N/A

### Related Policies

- MRI-Guided Focused Ultrasound for the Treatment of Uterine Fibroids and Other Tumors, #[243](#)

### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

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

- Evidence of uterine fibroids via ultrasound that are less than 10cm in diameter for laparoscopic RFA with Acessa<sup>TM</sup> or 7cm for transcervical RFA with Sonata<sup>TM</sup>, **AND**
- Individual 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**
- Individual has experienced **at least one** 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
  - Lower back pain
  - 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).

Other laparoscopic, transcervical, or percutaneous techniques for myolysis of uterine fibroids, including use of laser ablation or bipolar needles, cryomyolysis, and magnetic resonance imaging-guided laser ablation, are considered **INVESTIGATIONAL**.

Abnormal uterine bleeding refers to uterine bleeding of abnormal frequency, duration, and volume that interferes with an individual's quality of life. Individuals with abnormal uterine bleeding with an inadequate response to appropriately selected medical therapy may be considered for alternate uterine-sparing interventions. In individuals >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.

Clinical trial experience with radiofrequency ablation (RFA) has been limited to individuals with overall uterine size ≤16 gestational weeks size based on pelvic examination. In individuals where fibroids cannot be distinguished from adenomyosis on ultrasound, advanced imaging (e.g., magnetic resonance imaging [MRI]) may be required. For individuals 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. Individuals aiming to avoid future deliveries via obligate cesarean section may prefer a transcervical approach. Select individual with numerous fibroids may benefit from combined laparoscopic RFA and laparoscopic myomectomy. Individuals 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 (≥50% submucosal)
	2	≥50% intramural (<50% submucosal)
Other	3	100% intramural, contacting endometrium
	4	100% intramural, no endometrial or subserosal contact
	5	Subserosal, ≥50% intramural
	6	Subserosal, <50% intramural
	7	Pedunculated subserosal
	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 individuals 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.

**Prior Authorization Information**

### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is <b>not</b> required.
Commercial PPO and Indemnity	Prior authorization is <b>not</b> required.
Medicare HMO Blue <sup>SM</sup>	Prior authorization is <b>not</b> required.
Medicare PPO Blue <sup>SM</sup>	Prior authorization is <b>not</b> required.

### CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

**The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

### CPT Codes

CPT codes:	Code Description
58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency

### Description

#### Uterine Fibroids

Uterine fibroids, also known as leiomyomas, are among the most common conditions affecting individual in their reproductive years; symptoms include menorrhagia, pelvic pressure, or pain. It is estimated that uterine fibroids occur in up to 70% of individual by menopause, with approximately 25% of these being clinically significant and requiring intervention.<sup>1</sup> The prevalence rate of uterine fibroids is 2-3 times higher among Black individual compared with White individual, and there are higher rates of hysterectomy and myomectomy compared with non-surgical therapy, potentially demonstrating a disparity in access to uterine-sparing interventions.<sup>2,3</sup>

#### 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 and transcatheter magnetic resonance imaging-guided focused ultrasound therapy (see policy #243). 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.<sup>4</sup> 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.

## Summary

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 individuals. 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 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 ( $\leq 20$  individuals). 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-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.

Individual 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.

## Policy History

Date	Action
4/2022	Annual policy review. Policy statements clarified. Policy intent remains unchanged. Title changed to Laparoscopic, percutaneous, and transcervical techniques for uterine fibroid myolysis.
11/2020	Policy title clarified. Terminology for transcervical procedure clarified. Policy statements unchanged. 11/1/2020.
10/2020	New medically necessary indications added for laparoscopic and transcervical radiofrequency ablation for the treatment of uterine fibroids. Clarified coding information, 10/1/2020.
10/2019	Annual policy review. Description, summary and references updated. Policy statements unchanged.
10/2018	Annual policy review. No changes to policy statements. New references added. Background and summary clarified.
9/2017	Annual policy review. New references added.
1/2017	Clarified coding information for the 2017 code changes.
10/2016	Annual policy review. New references added.

8/2015	Annual policy review. New references added.
9/2014	Annual policy review. New references added.
6/2014	Coding information clarified.
10/2013	Annual policy review. New references added.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/2011	Reviewed - Medical Policy Group - Urology, Obstetrics and Gynecology. No changes to policy statements.
10/2010	Reviewed - Medical Policy Group - Obstetrics and Gynecology. No changes to policy statements.
7/2010	Medical Policy 244 effective 7/10 describing on-going non-coverage

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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