4.01.19	Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis		
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Section:	4.0 OB/Gyn/Reproduction	**Page:**	Page 1 of 33

Policy Statement

I. 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:
   A. 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
   B. 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]) (see Policy Guidelines)
   C. Individual has experienced at least **one** of the following symptoms that are a direct result of the fibroid(s):
      1. Menorrhagia or other abnormal uterine bleeding that interferes with daily activities or causes anemia (see Policy Guidelines)
      2. Pelvic pain or pressure
      3. Urinary symptoms (e.g., urinary frequency, urgency) related to bulk compression of the bladder
      4. Gastrointestinal symptoms related to bulk compression of the bowel (e.g., constipation, bloating)
      5. Dyspareunia (painful or difficult sexual relations)

II. 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, are considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Eligibility Considerations

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 greater than 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 patients with overall uterine size less than or equal to 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 individual

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 individuals 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. International Federation of Gynaecology and Obstetrics (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 (e.g., 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.

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.

Coding

The following codes might be used for a laparoscopic procedure:

- **58578:** Unlisted laparoscopy procedure, uterus
- **58674:** Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency
- **58999:** Unlisted procedure, female genital system (nonobstetrical)

For percutaneous procedures, the following code would likely be used to describe the magnetic resonance imaging component of the procedure:

- **77022:** Magnetic resonance imaging guidance for, and monitoring of, parenchymal tissue ablation

For ultrasound guidance, one of the following codes might be used:

- **76940:** Ultrasound guidance for, and monitoring of, parenchymal tissue ablation
- **76998:** Ultrasonic guidance, intraoperative

Description

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.

Related Policies

- Magnetic Resonance-Guided Focused Ultrasound

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

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 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 (e.g., Nd:YAG lasers, bipolar electrodes) have long-standing FDA approval, and there are no products specifically approved for the treatment of uterine fibroids.

Rationale

Background

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.[1,] The prevalence rate of uterine fibroids

is 2 to 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.[2,3,]

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 transcutaneous magnetic resonance imaging-guided focused ultrasound therapy (see evidence review 7.01.109).

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.[4,] 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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Radiofrequency Ablation

Clinical Context and Therapy Purpose

The purpose of radiofrequency ablation (RFA) in individuals who have uterine fibroids is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is women with symptomatic uterine fibroids.

Interventions

The therapy being considered is laparoscopic or transcervical RFA of fibroids under ultrasonic guidance.

Comparators

The following therapies are currently being used to manage symptomatic uterine fibroids: medical management, uterine artery embolization (UAE), myomectomy, and hysterectomy. Surgery, including hysterectomy and myomectomy, is considered the criterion standard for symptom resolution.

However, there is the need to recover from surgery, and in the case of a hysterectomy, the uterus is not preserved. UAE is associated with poor pregnancy outcomes and is not advised in patients who desire to become pregnant.

A retrospective cohort from claims data of over 35,000 women found that of the less invasive procedures, myomectomy had the lowest 12-month reintervention rate (4.2%), followed by UAE (7.0%), and endometrial ablation (12.4%).[5,]

Outcomes

The outcomes of interest are complications, postoperative pain and recovery time, symptom resolution, fibroid regrowth or recurrence and need for reintervention at 3 to 5 years, and health-related quality of life. The symptom severity score (SSS) is a 0 to 100 scale where higher SSSs indicate more severe symptoms. The EuroQol 5-Dimension (EQ-5D) is a 0 to 100 scale where lower scores indicate worse quality of life. Reinterventions may involve retreatment with RFA or other uterine-sparing techniques or definitive treatment with hysterectomy.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.
- Studies identify the relevant commercially-available technology.

Review of Evidence

Systematic Reviews

A systematic review and meta-analysis by Sandberg et al (2018) evaluated the risk of reintervention and quality of life after uterine-sparing interventions for fibroids (see Tables 1 and 2).[6,] Reintervention was defined as any additional treatment required at ≥1 year after initial treatment owing to symptomatic recurrence of fibroids. Reinterventions directly related to procedure complications and studies enrolling women with a prior history of fibroid interventions were excluded. Risk of

reintervention at 12 months was 0.3% for laparoscopic RFA compared with 3.6% for UAE and 1.1% for myomectomy. Symptom severity and quality of life scores were similar for the 3 treatments. Only 1 RFA study was identified on reintervention risk at 36 months (10.4%) which was comparable to UAE (7.4%; 95% confidence interval [CI], 0.9 to 10.7%); no RFA studies were identified on reintervention risk at 60 months. At 36 months, the reintervention risk for hysterectomy varied from 0.6% (95% CI, 0 to 2.3%; I^2=60.2%; 4 studies) for myomectomy to 8.1% for laparoscopic RFA (1 study). A systematic review by Havryliuk et al (2017) that did not separate outcomes by the length of follow-up found a reintervention rate of 5.2% after RFA (4 studies, 12 to 36 month follow-up) compared to 4.2% after myomectomy (6 studies, 12 to 52 month follow-up).[7,] There was no significant difference in complication rates between RFA (6.3%) and myomectomy (7.9%). The length of stay after myomectomy was 2 days (range, 0.5 to 6.0). No data were provided on the length of stay after RFA. Lin et al (2019) conducted a meta-analysis of improvement in symptom severity, quality of life, and reintervention after RFA.[8,] The review included 1 RCT (interim analysis only with high loss to follow-up) and 7 non-comparative trials. The reintervention risk at a weighted mean follow-up of 24.65 months (range, 3 to 36 months) was 4.4% (95% CI, 1.6 to 8.45%; I^2=65.0%; 7 studies). Improvements in symptoms and quality of life were maintained out to 24 months in 3 studies and out to 36 months in 1 study. No studies were identified that had follow-up longer than 36 months.

Bradley et al (2019) conducted a systematic review of 32 prospective studies on laparoscopic, transvaginal, or transcervical RFA.[9,] Most were conducted outside of the U.S. with devices that are not cleared or approved by the U.S. Food and Drug Administration. The overall reintervention risk was 4.2% at 12 months, 8.2% at 24 months, and 11.5% at 36 months. Reintervention rates at 12 months did not differ significantly for the laparoscopic, transvaginal, or transcervical RFA procedures. Because many of the devices are not available in the U.S., relevance for the current review is limited.

Transcervical RFA was evaluated in a qualitative systematic review by Arnreiter and Oppelt (2021).[10,] They included 10 studies that reported on myoma volume, patient-reported outcomes, surgical reinterventions, side effects, or safety during pregnancy and delivery. No RCTs were available to perform a meta-analysis. Single-arm studies (n=7, 5 prospective) and case reports (n=3) were evaluated with quality assessment tools; all the single-arm studies were considered to be of fair quality with a high risk of selection bias. Four studies reported on myoma volume, patient-reported symptoms, and reinterventions, 3 studies investigated the effect on surrounding tissue, and 3 articles were case reports on pregnancies after treatment with the transcervical system. Myoma volume, measured by contrast-enhanced magnetic resonance imaging (MRI), was reduced by an average 63.2% in total volume (n=157) and 64.5% (n=156) in perfused volume at 12 months. The symptom severity score was reduced by 55% at 12 months and similar improvement was maintained at 24 and 64 months. Health-related quality of life improved from 38.8 points before treatment to 83.3 points at 12 months (n=183). Reported re-intervention rates ranged from 0.7% to 8% at 12 months, 5.2% at 24 months, and 11.8% at 64 months after ablation, but loss to follow-up was high, limiting confidence in these results. Reporting of adverse events was incomplete; of 227 patients, 47.6% of patients experienced adverse events. Although most adverse events were mild, 4 patients required inpatient treatment. There was no reported evidence of wall thinning or scars, no significant change in uterine wall thickness, and no intrauterine adhesions (n=19 to 34). The authors identified case reports of 3 pregnancies after transcervical RFA with no complications. This systematic review is limited by the lack of available RCTs and high risk of bias in the published literature.

Zhang et al (2022) conducted a systematic review of minimally invasive interventions for uterine fibroid-related bleeding.[11,] A total of 15 studies for RFA were included (2 RCTs, 13 nonrandomized). Meta-analysis was not performed. The authors descriptively summarized that bleeding significantly decreased in severity in all studies after RFA (up to 12 months follow-up). In 3 studies that compared RFA to myomectomy (2 randomized, 1 nonrandomized), all patients experienced a decrease in fibroid-related bleeding with no difference between treatments (p>.05 in all cases).

Table 1. Characteristics of Systematic Reviews on Radiofrequency Ablation

Study	Dates	Trials	Participants	N	Design	Duration
Sandberg et al (2018)[6]	2006-2016	45	Women with symptomatic uterine fibroids undergoing myomectomy, UAE, or laparoscopic RFA	17,789	Studies evaluating any reintervention and quality of life with consecutive enrollment and follow-up of ≥12 mo	11.2 to 34.7 mo
Lin et al (2019)[8]	2000-2018	8	Women with symptomatic uterine fibroids undergoing myomectomy, UAE, or laparoscopic RFA	581	Studies evaluating symptoms and quality of life	>12 mo
Bradley et al (2019)[9]	2005-2019	32	Women with symptomatic uterine fibroids undergoing laparoscopic, transvaginal, or transcervical RFA	1283	Prospective studies for treatment of uterine fibroids with RFA (variety of devices)	12 to 36 mo
Arnreiter and Oppelt (2021)[10]	2011-2019	10	Women with symptomatic uterine fibroids undergoing transcervical RFA with the SONATA system	Range, 1 to 147	Studies that reported on myoma volume, patient-reported outcomes, surgical reinterventions, side effects, and safety during pregnancy and delivery	1 week to 64.4 mo

RFA: radiofrequency ablation; SONATA: sonography-guided transcervical ablation of uterine fibroids; UAE: uterine artery embolization

Table 2. Results of Systematic Reviews on Radiofrequency Ablation

Study	Reintervention Risk (95% CI), %			Change in SSS (95% CI)			Change in QOL (95% CI)	
	At 12 Months	At 36 Months	At 60 Months	At 12 Months	At 24 Months	At 36 Months	At 12 Months	At 24 Months
Sandberg et al (2018)[6]								
Total studies	40	8	27	18			11	
Myomectomy	1.1 (0.0 to 3.7)	1.2 (0.0 to 5.2)	12.2 (5.2 to 21.2)	-37.6 (-43.8 to -31.4)			39.9 (33.0 to 46.8)	
UAE	3.6 (2.4 to 4.9)	7.4 (0.9 to 10.7)	14.4 (9.8 to 19.6)	-35.8 (-40.6 to -30.9)			38.9 (35.8 to 41.9)	
Laparoscopic RFA	0.3 (0.0 to 1.6)	10.4 (1 study)	Unknown	-37.0 (-44.6 to -29.4)			35.1 (28.7 to 41.6)	
Lin et al (2019)[8]		Range, 3 to 36 mo						
Total Studies		7		6	3	1	3	1
Laparoscopic RFA		4.39 (1.60 to 8.45)		-39.37 (-34.70 to -44.04)	-33.51 (-22.24 to -44.78)	-32.60 (-27.75 to -37.45)	29.21 (12.44 to 45.98)	38.60 (33.60 to 39.79)
P Value				<.001	<.001	<.001	<.001	<.001
Bradley et al (2019)[9]								
Total Studies								
RFA (various)	4.2	11.5			-40		+39	
					<.001		<.001	
Arnreiter and Oppelt (2021)[10]								
Transcervical RFA				-55.1 (SD, 41.0)			277%	

CI: confidence interval; QOL: quality of life; RFA: radiofrequency volumetric thermal ablation; SD: standard deviation; SSS: Symptom Severity Score; UAE: uterine artery embolization.

Randomized Controlled Trials of Laparoscopic Radiofrequency Ablation

Studies of laparoscopic RFA include RCTs. One RCT evaluating laparoscopic RFA (Brucker et al, 2014)[12,] was included in the Sandberg et al (2018) systematic review;[6,] Tables 3 and 4 describe key RCT trial characteristics and results.

The Treatment Results of Uterine Sparing Technologies (TRUST) Canada post-market RCT compared laparoscopic RFA with laparoscopic myomectomy for the treatment of symptomatic fibroids. A 2018 publication by Rattray et al of TRUST included 45 patients (23 RFA, 22 myomectomy) and reported primarily on short-term resource utilization and return to work.[13,] RFA was found to be noninferior to laparoscopic myomectomy in the length of stay. Clinical outcomes at 3 months were improved by a similar percentage in both groups (-44.8%) and women treated with RFA required less time to return to work (11.1 vs. 18.5 days; p=.019). A post-market, prospective, single-arm analysis of the ongoing TRUST study reported by Yu et al (2020) surveyed 26 surgeons who performed 105 procedures with 100 per-protocol patients to capture surgical experiences and safety outcomes.[14,] Surgeons received proctored training during study run-in and provided self-assessments after performing ≥2 procedures at 4 to 8 weeks follow-up. No acute serious adverse events (≤48 hours) were reported compared with 2 (1.46%) in the premarket study. Both studies reported 1 (<1%) serious adverse event within 30 days of the procedure. No efficacy outcomes were reported.

Yu et al (2022) published a preliminary analysis of the ongoing TRUST United States trial, which is an RCT comparing laparoscopic RFA or myomectomy in patients with uterine myoma with a planned follow-up of 5 years.[15,] The preliminary analysis after 12 months of follow-up included 29 patients who underwent laparoscopic RFA and 27 patients who underwent myomectomy. At baseline, the mean myoma size was 3.1 cm in the RFA group and 3.5 cm in the myomectomy group and about 95% of patients had symptoms. The primary outcome of the TRUST United States trial is length of hospital stay, which was significantly shorter in the laparoscopic RFA group (8.0 ± 5.7 hours) than the myomectomy group (18.8 ± 14.6 hours; p<.05). The outcomes of interest for the preliminary analysis were symptoms and patient reported quality of life outcomes at 12 months. Symptoms improved in both groups at both 3 and 12 months after the procedure with no statistical difference between groups. Symptom severity and health-related quality of life were significantly better in the myomectomy group at 12 months. Major complications occurred in 2 patients who underwent myomectomy and 1 patient who underwent laparoscopic RFA. One reintervention was needed (in the laparoscopic RFA group).

Table 3. Summary of Key Randomized Controlled Trial Characteristics for Laparoscopic Radiofrequency Ablation

					Interventions	
Study	**Countries**	**Sites**	**Dates**	**Participants[a]**	**Active**	**Comparator**
Brucker et al (2014)[12,]; Hahn et al (2015)[16,]; Kramer et al (2016)[17,]	Germany	1	2012-2013	• ≥18 y • Menstruating • Symptomatic uterine fibroids <10 cm • Uterine size ≤16 gestational wk • Desire uterine conservation • Not pregnant or lactating • Race or ethnicity: 100% White	RFA=26	LM=25
Rattray et al (2018)[13,](TRUST Canada)	Canada	Multiple	2012-2017	• ≥18 y • Menstruating	RFA=23	LM=22

					Interventions	
				• Symptomatic uterine fibroids <10 cm • Uterine size ≤16 gestational wk • Desire uterine conservation • Not pregnant or lactating • Race or ethnicity: 76% White, 11% Black, 4% Asian, 2% Other, 0% Latino/Hispanic		
Yu et al (2022)[15,](TRUST United States)	United States	Multiple	2014-2019	• ≥18 y • Symptomatic uterine fibroids <10 cm • Uterine size ≤16 gestational wk • Desire uterine conservation • Not pregnant or lactating • Race or ethnicity: 26% to 48% White, 44% to 47% Black, 0% to 13% Asian, 3% to 7% Other, 3% to 7% Latino/Hispanic	RFA=29	LM=27

LM: laparoscopic myomectomy; RFA: radiofrequency volumetric thermal ablation; TRUST: Treatment Results of Uterine Sparing Technologies.
[a] Key eligibility criteria.

Table 4. Summary of Key Randomized Controlled Trial Outcomes for Laparoscopic Radiofrequency Ablation

Study	Primary Outcome	Secondary Outcomes			
	Hospital LOS (SD), hours	Mean SSS		Mean HRQOL	
		12 months	24 months	12 months	24 months
Brucker et al (2014)[12,]; Hahn et al (2015)[16,]; Kramer et al (2016)[17,]	50	43[a]	43	43	43
Laparoscopic RFA	10.0 (5.5)	24.7	16	87	89.4
Laparoscopic myomectomy	29.9 (14.2)	26	22.3	83	85.6
p	<.001[b]	NS[c]	NS	NS	NS
Rattray et al (2018)[13,](TRUST Canada)					
Laparoscopic RFA	6.7 (3.0)				
Laparoscopic myomectomy	9.9 (10.7)				
p	<.001				
Yu et al (2022)[15,] (TRUST United States)					
Laparoscopic RFA	8.0 (5.7)	23.4	NR	78.7	NR
Laparoscopic myomectomy	18.8 (14.6)	12.1	NR	95.6	NR
p	<.05	<.05		<.05	

HRQOL: health-related quality of life; LOS: length of stay; NR: not reported; NS: not significant; RFA: radiofrequency volumetric thermal ablation; SD: standard deviation; SSS: Symptom Severity Score; TRUST: Treatment Results of Uterine Sparing Technologies.
[a] Analyses at 12 and 24 months were per protocol and included 84% of randomized participants.
[b] Met criteria for noninferiority: hospital LOS after RFA no more than 10% longer than after laparoscopic myomectomy.
[c] Exact between-group p values were not reported.

In the Brucker et al (2014) trial,[12,] all patients in the myomectomy group were hospitalized overnight; although not explicitly stated, this appeared to be the standard procedure at the study hospital. In the laparoscopic RFA (Acessa) group, there was an unplanned hospitalization due to unexplained vertigo and 4 hospitalizations as a standard procedure because the patients also underwent adhesiolysis. It is unclear whether these abdominal adhesions were due to prior surgical interventions for uterine fibroid myolysis; however, patients with significant intra-abdominal adhesions and known or suspected endometriosis or adenomyosis were excluded from the study.

Secondary outcomes of the RCT were reported by Hahn et al (2015)[16,] (12-month outcomes) and by Kramer et al (2016)[17,] (12-month and 24-month outcomes). In addition to summary symptom and quality of life measures, the publications reported on 11 symptoms: heavy menstrual bleeding, increased abdominal girth, dyspareunia, pelvic discomfort/pain, dysmenorrhea, urinary frequency, urinary retention, sleep disturbance, backache, localized pain, and "other symptoms" (not specified). Limitations of the 12- and 24-month analyses, shown in Tables 5 and 6, included lack of intent-to-treat analysis and failure to describe secondary study hypotheses and statistical analyses clearly. The RCT had a small sample size and thus might have been underpowered to detect clinically meaningful differences in secondary outcomes, so these results do not rule out potential differences between treatments.

Table 5. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Brucker et al (2014)[12,]; Hahn et al (2015)[16,]; Kramer et al (2016)[17,]	4. Enrolled populations do not reflect relevant diversity.				1. Insufficient to determine reintervention rates
Rattray et al (2018)[13,](TRUST Canada)					
Yu et al (2022)[15,] (TRUST United States)					

TRUST: Treatment Results of Uterine Sparing Technologies
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 6. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Brucker et al (2014)[12]; Hahn et al (2015)[16]; Kramer et al (2016)[17]				6. Not intent-to-treat	1. Power for secondary outcomes unclear	
Rattray et al (2018)[13](TRUST Canada)		1, 2, 3. No blinding				
Yu et al (2022)[15] (TRUST United States)		1, 2, 3. No blinding				

TRUST: Treatment Results of Uterine Sparing Technologies
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Prospective Single Arm Studies of Laparoscopic Radiofrequency Ablation

Berman et al (2014) reported long-term results of the LAP-RFA trial (also known as the HALT trial), which prospectively evaluated the Acessa system for laparoscopic RFA in premenopausal patients (n=135) with uterine myomas and heavy menstrual bleeding.[18] Myoma size ranged from 0.7 to 9.7 cm. After 36 months of follow-up (n=104), mean symptom severity decreased by 32.6 points (p<.001) and health-related quality of life was significantly improved (p<.001). Reintervention was needed in 11% (14 of 135) of patients in the full cohort. Berman et al (2022) reported on a subgroup analysis of the HALT trial and found a higher disease burden among Black women (n=46) at baseline compared to White women (n=28) based on both symptom score (p≤.001) and health-related quality of life (p=.005).[19] At 36 months, there were no significant differences in symptom scores or health-related quality of life between groups.

Jacoby et al (2020) surveyed gynecologist experience and health outcomes following adoption of laparoscopic RFA into clinical practice for 26 patients across 5 academic medical centers in California in the Uterine Leiomyoma Treatment with Radiofrequency Ablation (ULTRA) trial.[20] Eligibility criteria included women ≥21 years of age seeking uterine-sparing surgical treatment of leiomyomas for heavy bleeding, pelvic pressure or discomfort, urinary or bowel symptoms, or dyspareunia. Women seeking future fertility were informed that there are insufficient data to determine the impact of treatment on fertility outcomes. No intraoperative complications or major adverse events were reported. Significant improvements in menstrual bleeding, sexual function, and quality of life were reported from baseline to 12 weeks, with a 47% decrease in the Leiomyoma Symptom Severity Score. Self-rated mean procedure difficulty score decreased from 6 to 4.25 following the fourth procedure among general gynecologists new to the technology. The authors concluded that laparoscopic RFA can be introduced into clinical practice with good clinical outcomes.

Prospective Single Arm Studies of Transcervical Radiofrequency Ablation

Studies of transcervical RFA are limited to prospective single-arm studies (see Tables 7 and 8). The pivotal study for the Sonata transcervical RFA system (sonography-guided transcervical ablation of

uterine fibroids [SONATA]) was a prospective single-arm study with 147 premenopausal women who had symptomatic uterine fibroids (1 to 5 cm) with heavy menstrual bleeding.[21,] Patients were excluded if they desired to become pregnant. There were 2 (1.4%) procedure-related adverse events during the first year of follow-up and no additional device-related adverse events between the 1- and 2- year follow-up. At the 24 month follow-up, patients reported significantly improved SSS, health-related quality of life, and EQ-5D. The cumulative rate of surgical intervention for heavy menstrual bleeding was 5.2% (95% CI, 2.5% to 10.6%). Follow-up at 3 years showed a reintervention rate of 8.2%.[22,] In patients who did not undergo reintervention, menopause, or withdrawal (not last observation-carried-forward), the gains observed at the 2-year follow-up were maintained at 3 years. In the 105 patients (71%) who remained in the trial, significant improvements in the SSS (p<.001), health-related quality of life (p<.001), quality of life (p<.001), work absenteeism (p<.001), impairment for work (p<.001), and physical activity (p<.001) were maintained. These results are limited by the loss to follow-up in the 3-year results.

The Fibroid Ablation Study EU (FAST-EU) was a prospective single-arm trial with the previously named VizAblate transcervical RFA.[23,] Fifty women who had heavy menstrual bleeding were included in the study. Up to 5 fibroids sized between 1 and 5 cm could be treated. Patients were excluded if they desired to become pregnant. The primary outcome measure, that at least 50% of patients with >30% reduction in perfused fibroid volume, was achieved at the 3-month follow-up. Twelve-month follow-up was not in the original study design, and only 28 (58.3%) of participants agreed to return for an MRI at this time point. Symptom Severity Scores were obtained in all patients except for 1 patient due to pregnancy. A clinically significant minimum 10 point reduction in the SSS was obtained in 82% of patients at 3 months, 86% at 6 months, and 78% at 12 months. There were 34 adverse events deemed possibly, probably, or definitely related to the procedure. Four patients (8%) underwent surgical reintervention between 6 and 12 months post-ablation.

Shifrin et al (2021) conducted a subgroup analysis of patients with submucous (type 1, 2, or 2-5) or large fibroids (> 5 cm) from patients in the FAST-EU and SONATA clinical trials.[24,] In total, 72.5% of the 534 treated fibroids were not amenable to hysteroscopic resection because they were intramural, transmural, or subserous. At 3 month follow-up, 86% of women with only submucous fibroids and 81% of women with large fibroids experienced bleeding reduction. At 12 month follow-up, a reduction in menstrual bleeding was found in 92% to 96% of women with submucous fibroids and 86% to 100% of women with large fibroids (although fibroids >5 cm was an exclusion in SONATA, 2.5% [n=11] of patients were in this category). Improvement in the SSS, health-related quality of life, and EQ-5D were also noted in these subgroups. Rates of surgical reintervention for women with submucous fibroids was less than 3.7%.

The Transcervical Radiofrequency Ablation of Uterine Fibroids Global Registry (SAGE) will enroll 500 patients treated with transcervical RFA at up to 50 sites in Europe (NCT03118037). Participation in the registry requires willingness to return for follow-up visits through 5 years, with no restrictions for participation based on patient age (>18), fibroid type and size, prior surgical history, or desire for future fertility. Characteristics and adverse events from the first 160 women in the registry were reported by Christoffel et al (2021).[25,] A total of 241 fibroids were treated with another 271 identified by sonography but not ablated. Fibroid size ranged from <1 cm to >10 cm, with 27% of fibroids having a diameter of >5 cm. Patients will be followed for 5 years.

Table 7. Summary of Single-Arm Study Characteristics for Transcervical Radiofrequency Ablation

Study	Study Location	Participants	Treatment Delivery	Follow-Up
Brolmann et al (2016) [23,](FAST-EU)	7 community or academic gynecologists in EU and Mexico	50 women ≥28 years of age with heavy menstrual bleeding for at least 3 months and no desire to become pregnant	VizAblate transcervical RFA	12 mo

Study	Study Location	Participants	Treatment Delivery	Follow-Up
Miller et al (2020)[21,22,](SONATA)	24 community or academic gynecologists from 21 centers in the US and Mexico	147 premenopausal women 25 to 50 years of age with symptomatic uterine fibroids (1 to 5 cm) with heavy menstrual bleeding and no desire to become pregnant	Sonata transcervical RFA	3 years
Christoffel et al (2021)[25,](SAGE)	Registry from 50 sites in Europe	First 160 of 500 women ≥18 years of age who select transcervical RFA for symptomatic uterine fibroids and agree to follow-up	Sonata transcervical RFA	5.3 mo (range, 0.1 to 25.0)

FAST-EU: Fibroid Ablation Study EU; RFA: radiofrequency ablation; SAGE: Transcervical Radiofrequency Ablation of Uterine Fibroids Global Registry; SONATA: sonography-guided transcervical ablation of uterine fibroids

Table 8. Summary of Single Arm Study Results for Transcervical Radiofrequency Ablation

Study	Baseline	3 mo	12 mo	24 mo	36 mo
Brolmann et al (2016) [23,FAST-EU					
n (%)	50	50	48		
Percentage change in perfused fibroid volume (SD)	18.3 (20.6)	5.8 (9.6)	6.6 (11.3) n=28		
Symptom Severity Score (SD)	61.7 (16.9)	31.7 (20.1)	26.6 (24.0)		
HRQL	34.3 (19.0)	76.4 (22.2)	80.7 (24.7)		
Surgical reintervention			4 (8%)		
Miller et al (2020)[21,22,](SONATA)					
n (%)	147			125 (85%)	105 (71%)
SSS (SD)	55 (19)	27 (19) p<.001		24 (18) p<.001	22 (21) p<.001
HRQL (SD)	40 (21)	78 (22) p<.001		83 (19) p<.001	83 (23)
EQ-5D (SD)	0.72 (0.21)	0.87 (0.13) p<.001		0.89 (0.14) p<0.001	0.88 (0.16)
Surgical reintervention				5.5%	8.2%

EQ-5D Euroqol 5-dimension; HRQL: Health-related quality of life; FAST-EU: Fibroid Ablation Study EU; RFA: radiofrequency ablation; SAGE: TransScervical Radiofrequency Ablation of Uterine Fibroids Global Registry; SD: standard deviation; SONATA: sonography-guided transcervical ablation of uterine fibroids; SSS: Symptom Severity Score

Pregnancy Outcomes After Radiofrequency Ablation

Keltz et al (2017) published a systematic review of published literature on pregnancy outcomes after thermal ablation of uterine fibroids.[26,] For laparoscopic RFA, reviewers identified 20 pregnancies reported in 4 case series; the denominator (i.e., the number of patients treated in these series) was not reported. Of the 20 pregnancies, 7 were undesired and were electively terminated. For the remaining 13 pregnancies, there was 1 spontaneous abortion and 12 full-term births. Nine of the 12 live births were cesarean delivery.

Polin et al (2022) conducted a systematic review of published reports of pregnancy outcomes following RFA for uterine myomas.[27,] Ten publications reported the outcome of 40 pregnancies that occurred after laparoscopic RFA and 10 pregnancies that occurred after transcervical RFA. Outcomes included 44 full-term deliveries (24 vaginal, 20 cesarean) and 6 spontaneous abortions. Two delivery complications occurred (1 placenta previa, 1 delayed postpartum hemorrhage). No cases of uterine rupture or fetal complications occurred.

Berman et al (2020) conducted a retrospective review of pregnancy delivery and safety after laparoscopic RFA of uterine fibroids.[28,] The review included results from 2 RCTs, 6 cohort studies, and commercial cases (total N=28) that evaluated rates of spontaneous abortion, preterm delivery, postpartum hemorrhage, placental abnormalities, intrauterine growth restriction, and rates of cesarean delivery. Thirty pregnancies resulted in 26 full-term births (86.7%), with an equal distribution

of vaginal and cesarean deliveries, and the spontaneous abortion rate (13.3%) was within the range for the general population. There were no cases of preterm delivery, uterine rupture, placental abruption, placenta accreta, or intrauterine growth restriction. One patient experienced severe postpartum hemorrhage. While these retrospective results did not identify any safety signals for pregnancy, ongoing prospective studies that are evaluating pregnancy outcomes will provide more confidence in pregnancy outcomes after laparoscopic RFA.

Christoffel et al (2022) reported pregnancy outcomes among 28 women who received transcervical RFA with the Sonata system in either a clinical trial or real-world setting.[29,] Outcomes of the 36 pregnancies included 20 deliveries (8 vaginal, 12 cesarean), 3 induced abortions, and 8 first trimester spontaneous abortions. Half of the spontaneous abortions occurred in a single patient with a history of recurrent pregnancy loss. Nineteen of the 20 deliveries were full term. No cases of uterine rupture, postpartum hemorrhage, or stillbirth occurred.

Section Summary: Radiofrequency Ablation

Prospective case series, systematic reviews, and RCTs comparing RFA with laparoscopic myomectomy have been published. The meta-analyses found low rates of reintervention with RFA and quality of life outcomes that were similar to myomectomy and UAE at 12 months. Data on reintervention rates is limited, including reinterventions for hysterectomy. Two RCTs found that RFA was noninferior to laparoscopic myomectomy on the primary outcome (length of hospitalization). A number of secondary outcomes of 1 RCT were reported at 12 and 24 months, including symptoms and quality of life outcomes; none differed significantly between groups. The RCT only had 43 patients in subgroup analyses at 12 and 24 months and may have had insufficient power for the secondary outcomes. The procedure is associated with a reduction in symptoms and improvement in quality of life in the short-term. The reintervention rate at longer follow-up is unknown. Because most trials excluded women who desired to become pregnant, the impact of RFA on pregnancy outcomes is uncertain. Additional well-designed comparative trials with longer follow-up are needed to determine the effect of RFA on health outcomes compared with other treatment options, including myomectomy.

Laser or Bipolar Needles

Clinical Context and Therapy Purpose

The purpose of therapy with laser or bipolar needles in individuals who have uterine fibroids is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is women with symptomatic uterine fibroids.

Interventions

The therapy being considered is laser or bipolar needles.

Comparators

The following therapies are currently being used to manage symptomatic uterine fibroids: medical management, UAE, myomectomy, and hysterectomy. Surgery, including hysterectomy and myomectomy, is considered the criterion standard for symptom resolution. However, there is the need to recover from surgery, and in the case of a hysterectomy, the uterus is not preserved. UAE is associated with poor pregnancy outcomes and is not advised in patients who desire to become pregnant.

A retrospective cohort from claims data of over 35,000 women found that of the less invasive procedures, myomectomy had the lowest 12-month reintervention rate (4.2%), followed by UAE (7.0%), and endometrial ablation (12.4%).[5,]

Outcomes

The outcomes of interest are complications, postoperative pain and recovery time, symptom resolution, need for reintervention, and health-related quality of life. The immediate follow-up would be a week for postoperative pain and recovery, and 3 to 5 years of follow-up would be needed to monitor for fibroid recurrence and retreatment.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Case Series

Several case series were identified, most published in the 1990s. For example, Goldfarb (1995) reported on outcomes for 300 women with symptomatic fibroids no larger than 10 cm who underwent myolysis using either Nd:YAG or bipolar needles. [30,] The author reported that the coagulating effect of the bipolar needle devascularized the fibroids, and the resulting shrinkage was comparable to that produced by Nd:YAG laser. An earlier study by Goldfarb (1992), included 75 patients who presented with symptomatic fibroids 5 to 10 cm in diameter.[31,] Symptoms included pelvic pain, pressure, dyspareunia, and recurrent menorrhagia. The Nd:YAG laser was inserted into the fibroid multiple times (eg, 75 to 100 punctures to coagulate a 5-cm fibroid). Based on an assessment by endovaginal ultrasound, the fibroids regressed in size and, after 6 to 14 months of follow-up, the size remained stable. No patient experienced significant complications. Nisolle et al (1993) reported on a case series of 48 women offered myolysis instead of myomectomy if they had completed childbearing.[32,] The authors reported that maximal decrease in fibroid size had occurred by 6 months ; however, as reported, it is unclear among the 28 of 48 patients with more than 2 fibroids whether all fibroids were treated in each patient, and, if not, how treated fibroids were selected. Additionally, no associated patient symptoms were reported.

Several authors have reported pelvic adhesions as a complication of the Nd:YAG laser procedure, presumably due to thermal damage to the serosal surface. In addition, the Nd:YAG laser produces a significant amount of smoke, which can obscure visibility.[33,34,]

Section Summary: Laser or Bipolar Needles

The evidence based on the use of lasers or bipolar needles only includes case series, small in size, and published in the 1990s. RCTs comparing laser and bipolar needles with alternative treatments for uterine fibroids and reporting health outcomes are needed.

Cryomyolysis

Clinical Context and Therapy Purpose

The purpose of cryomyolysis in individuals who have uterine fibroids is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is women with symptomatic uterine fibroids.

Interventions
The therapy being considered is cryomyolysis. Cryomyolysis entails inserting a -180°C cryoprobe into the center of a fibroid, which creates an "iceball" within the fibroid. Several freeze-thaw cycles are typically used, and the process may not be standardized.

Comparators
The following therapies are currently being used to manage symptomatic uterine fibroids: medical management, UAE, myomectomy, and hysterectomy. Surgery, including hysterectomy and myomectomy, is considered the criterion standard for symptom resolution. However, there is the need to recover from surgery, and in the case of a hysterectomy, the uterus is not preserved. UAE is associated with poor pregnancy outcomes and is not advised in patients who desire to become pregnant.

A retrospective cohort from claims data of over 35,000 women found that of the less invasive procedures, myomectomy had the lowest 12-month reintervention rate (4.2%), followed by UAE (7.0%), and endometrial ablation (12.4%).[5,]

Outcomes
The outcomes of interest are complications, postoperative pain and recovery time, symptom resolution, need for reintervention, and health-related quality of life. The immediate follow-up would be a week for postoperative pain and recovery, and 3 to 5 years of follow-up would be needed to monitor for fibroid recurrence and retreatment.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Case Series
No controlled studies evaluating cryomyolysis were identified.

Two case series have been identified. Zreik et al (1998)[35,] published a prospective pilot study with 14 patients, and Zupi et al (2004)[36,] presented their experience with 20 patients.[35,36,] In both case series, the authors reported that patients had symptom resolution. In the Zreik et al (1998) series, cryomyolysis maintained or slightly reduced the myoma volume by 6%. In the Zupi et al (2004) study, cryomyolysis was associated with a 25% reduction in fibroid size. Zupi et al (2005) reported on the 1-year follow-up of these patients.[37,] Mean shrinkage in fibroid size continued until 9 months after surgery, to a mean volume reduction of 60%. In the Sandberg et al (2018) systematic review (discussed above), the risk of reintervention was 15%.[6,] Interpretation of these studies is limited due to their small sample sizes and lack of comparison groups.

Section Summary: Cryomyolysis
The literature on cryomyolysis includes small case series, with no literature identified in the last decade. Controlled studies comparing cryomyolysis with alternative treatments for uterine fibroids and differentiating between outcomes related to fibroid treatment and outcomes related to the treatment of abnormal bleeding are needed.

Magnetic Resonance Imaging-Guided Laser Ablation

Clinical Context and Therapy Purpose

The purpose of MRI-guided laser ablation in individuals who have uterine fibroids is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is women with symptomatic uterine fibroids.

Interventions

The therapy being considered is MRI-guided laser ablation.

Comparators

The following therapies are currently being used to manage symptomatic uterine fibroids: medical management, UAE, myomectomy, and hysterectomy. Surgery, including hysterectomy and myomectomy, is considered the criterion standard for symptom resolution. However, there is the need to recover from surgery, and in the case of a hysterectomy, the uterus is not preserved. UAE is associated with poor pregnancy outcomes and is not advised in patients who desire to become pregnant.

A retrospective cohort from claims data of over 35,000 women found that of the less invasive procedures, myomectomy had the lowest 12-month reintervention rate (4.2%), followed by UAE (7.0%), and endometrial ablation (12.4%).[5,]

Outcomes

The outcomes of interest are complications, postoperative pain and recovery time, resolution of symptoms, need for reintervention, and health-related quality of life. The immediate follow-up would be a week for postoperative pain and recovery, and 3 to 5 years of follow-up would be needed to monitor for fibroid recurrence and retreatment.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Nonrandomized Studies

No RCTs evaluating MRI-guided laser ablation were identified. A nonrandomized study by Hindley et al (2002) was identified (see Tables 9 and 10).[38,] Results from the women treated with MRI-guided laser ablation were compared with a historical control group of 43 women who underwent a hysterectomy. Compared with the historical control group, the total score on the Menorrhagia Outcomes Questionnaire was significantly lower (i.e., worse outcomes) in those undergoing percutaneous myolysis. The quality of life subscores did not differ statistically.

Table 9. Summary of Key Nonrandomized Trial Characteristics

Study	Type	Country	Participants	Treatment	Comparator	FU, y
Hindley et al (2002)[38,]	Cohort with historical controls	U.K.	109 women with symptomatic fibroids seeking to avoid surgery	66 to MRI-guided laser ablation	43 to hysterectomy	1

FU: follow-up; MRI: magnetic resonance imaging.

Table 10. Summary of Key Nonrandomized Trial Results

Study	Mean Fibroid Volume Reduction (Range), %		MOQ Total	MOQ QOL/Satisfaction
	At 3 Months	At 1 Year		
Hindley et al (2002)[38,]				
n/N (%)	47/66 (71)	24/66 (36)	34/66	33/66
MRI-guided laser ablation	-31 (21 to -76)	-41 (13 to -78)	51.5	51.5
Hysterectomy	NR	NR	48.7	49.0
p			.02	.06

MRI: magnetic resonance imaging; MOQ: Menorrhagia Outcomes Questionnaire; NR: not reported; QOL: Quality of Life.

The purpose of the limitations tables (see Tables 11 and 12) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of the evidence supporting the position statement.

Table 11. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Hindley et al (2002)[38,]					1. Not sufficient duration to assess reintervention

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 12. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Hindley et al (2002)[38,]	1-4. Not randomized, inadequate control for selection bias	1-3. Not blinded		1.High loss to follow-up		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Section Summary: MRI-Guided Laser Ablation

A single nonrandomized study with historical controls was identified. Data reporting was incomplete, and self-reported outcomes were worse compared with a historical control group of women undergoing a hysterectomy. RCTs comparing MRI-guided laser ablation with alternative treatments for uterine fibroids and reporting health outcomes are needed.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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 for the following indication:
Women 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 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;
    - 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.

Further details from clinical input are included in the Appendix.

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 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, NICE published an interventional procedures guidance on the use of transcervical ultrasound-guided RFA for symptomatic uterine fibroids.[39,] The NICE guidance 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, 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 13.

Table 13. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03118037[a]	Transcervical Radiofrequency Ablation of Uterine Fibroids Global Registry (SAGE)	100	Dec 2028
NCT02163525[a]	The TRUST (Treatment Results of Uterine Sparing Technologies) U.S.A. Study	114	Jun 2024
NCT02100904	Uterine Leiomyoma Treatment With Radiofrequency Ablation (ULTRA) Registry (ULTRA Registry)	578	Aug 2025
Unpublished			
NCT02260752	Patient-Centered Results for Uterine Fibroids (COMPARE-UF)	3,094	Apr 2020 (last update Nov 2020)
NCT01563783[a]	The Trust (Treatment Results of Uterine Sparing Technologies) Study	84	Jun 2022

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

Appendix 1

2021 Clinical Input

CI-Objective

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 an improvement in the net health outcome and whether the use is consistent with generally accepted medical practice.

Respondents

Clinical input was provided by the following specialty societies and physician members identified by a specialty society or clinical health system:

- American College of Obstetrics and Gynecology (ACOG)
- Alison F. Jacoby, MD; Professor of Gynecology and Minimally Invasive Gynecologic Surgery; Director of Gynecologic Surgery and the Comprehensive Fibroid Center at the University of California, San Francisco (UCSF) Medical Center
- Anonymous, MD; Advanced Gynecology and Minimally Invasive Gynecologic Surgery; affiliated with an academic medical center

Clinical input provided by the specialty society at an aggregate level is attributed to the specialty society. Clinical input provided by a physician member designated by a specialty society or health system is attributed to the individual physician and is not a statement from the specialty society or health system. Specialty society and physician respondents participating in the Evidence Street® clinical input process provide review, input, and feedback on topics being evaluated by Evidence Street. However, participation in the clinical input process by a specialty society and/or physician member designated by a specialty society or health system does not imply an endorsement or explicit agreement with the Evidence Opinion published by BCBSA or any Blue Plan.

Ratings

Clinical Indication	Respondent	Identified by	Confidence Level That Clinical Use Expected to Provide Clinically Meaningful Improvement in Net Health Outcome: Yes or No	NO: High 5	4	Intermediate 3	2	Low 1	YES: Low 1	2	Intermediate 3	4	High 5	Confidence Level that Clinical Use is Consistent with Generally Accepted Medical Practice: Yes or No	NO: High 5	4	Intermediate 3	2	Low 1	YES: Low 1	2	Intermediate 3	4	High 5
Use of laparoscopic or transcervical radiofrequency ablation in women with symptomatic uterine fibroids	ACOG		Yes									■		Yes									■	
	Dr. Jacoby	UCSF	Yes									■		Yes									■	
	Anonymous	AMC	Yes										■	Yes										■

ACOG: American College of Obstetrics and Gynecology; AMC: academic medical center; UCSF: University of California San Francisco Medical Center.

Respondent Profile

	Specialty Society	
#	Name of Organization	Clinical Specialty
1	American College of Obstetrics and Gynecology (ACOG)	Obstetrics and Gynecology

#	Physician Name	Degree	Institutional Affiliation	Clinical Specialty	Board Certification and Fellowship Training
2	Alison F. Jacoby	MD	Professor of Gynecology and Minimally Invasive Gynecologic Surgery; Director, Comprehensive Fibroid Center at UCSF Medical Center	Obstetrics and Gynecology	Obstetrics and Gynecology
3	Anonymous	MD	Academic medical center	Advanced Gynecology and Minimally Invasive Gynecologic Surgery	Obstetrics and Gynecology; Minimally Invasive Gynecologic Surgery

Respondent Conflict of Interest Disclosure

#	1) Research support related to the topic where clinical input is being sought		2) Positions, paid or unpaid, related to the topic where clinical input is being sought		3) Reportable, more than $1,000, health care–related assets or sources of income for myself, my spouse, or my dependent children related to the topic where clinical input is being sought		4) Reportable, more than $350, gifts or travel reimbursements for myself, my spouse, or my dependent children related to the topic where clinical input is being sought	
	YES/NO	Explanation	YES/NO	Explanation	YES/NO	Explanation	YES/NO	Explanation
2	No		No		No		No	
3	No		No		No		No	

#	Conflict of Interest Policy Statement
1	The ACOG Committee on Health Economics & Coding provided the input for this document. There were no conflicts disclosed in the committee review.

Individual physician respondents answered at individual level. Specialty Society respondents provided aggregate information that may be relevant to the group of clinicians who provided input to the Society-level response.

Responses

Question 1.

We are seeking your opinion on whether using laparoscopic or transcervical radiofrequency ablation (RFA) for individuals with symptomatic uterine fibroids provides a clinically meaningful improvement in net health outcome. Please respond based on the evidence and your clinical experience. Please address these points in your response:

- Relevant clinical scenarios (e.g., a chain of evidence) where the technology is expected to provide a clinically meaningful improvement in net health outcome;
- Specific outcomes that are clinically meaningful;
- Any relevant patient inclusion/exclusion criteria or clinical context important to consider in identifying individuals for this indication; and
- Supporting evidence from the authoritative scientific literature (please include PMID).

#	Rationale
1	In June 2021, the ACOG Practice Bulletin: Management of Symptomatic Uterine Leiomyomas indicates that laparoscopic 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". Additionally, the Bulletin indicates that all approaches for RFA are similarly effective in reducing uterine fibroids and in improving quality of life metrics, with laparoscopic RFA being studied most rigorously. Two recently published meta-analyses found uterine fibroid volume reduction attributed to laparoscopic RFA ranged from 32% to 66% at 12 months post-operative, and 77% beyond 12 months. Cumulative rates for postoperative reintervention was fibroid-related symptom in one of the studies was 4.2%, 8.2%, and 11.5% at one, two, and three years follow-up, respectively. Additionally, statistically and clinically significant improvements were observed in health-related quality of life and symptom severity in long-term follow-up. In a separate systematic review and meta-analysis, laparoscopic RFA demonstrated major improvements in health-related quality of life and symptom severity scores compared to similar reports of other interventions, such as hysterectomy, myomectomy, and uterine artery embolization.While the recommendation set forth in the ACOG Practice Bulletin is categorized as Level B (a recommendation based on limited or inconsistent scientific evidence), the procedure of laparoscopic RFA is explicitly indicated as a reasonable option for consideration in the treatment of uterine fibroids. Additionally, ACOG does not consider this procedure experimental, investigational, or unproven.Furthermore, the CPT code 58674 laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency is a CPT Category I code. Category I procedure codes must meet specific criteria related to the procedure including documentation of clinical efficacy and is performed by many physicians and other health care professionals.Patients suffering from uterine fibroids should be afforded the option of all medically proven and appropriate treatment options, including laparoscopic RFA. An estimated 26 million women in the U.S. between the ages of 15 and 50 experience uterine fibroids, with Black women experiencing fibroids up to three times more frequently than other racial groups. Uterine fibroids are the most common solid and symptomatic neoplasm in women, occurring in up to 70% of women by menopause, and are the leading indication for hysterectomy. It has been estimated that the total annual direct cost of fibroids in the US is above $2 billion, mostly due to inpatient care and hysterectomy. Alternative treatment options to hysterectomy in patients suffering from uterine fibroids, including RFA approaches, have significantly lower costs compared to hysterectomy. Expanding treatment options for these patients only improves access to minimally invasive procedures at lower associated costs and comparable improvements to quality of life, with potential impacts on health equity and disparities in care.As described in the Practice Bulletin, the data on future pregnancy outcomes following RFA is limited. Small case series have not identified significant risk of complications or adverse outcomes, but the data are not robust. The desire for future pregnancy is not a contraindication to RFA, but patients should be counseled about the limited data. A recently released assessment from the American Association of Gynecologist Laparoscopists (AAGL) found that in a review of available literature, rare major complications and reintervention rates for patients receiving laparoscopic RFA are low and metrics such as fibroid volume, bleeding, pain, bulk symptoms, and overall quality of life improve after laparoscopic RFA. References - Management of symptomatic uterine leiomyomas. ACOG Practice Bulletin No. 228. American College of Obstetricians and Gynecologists. Obstet Gynecol 2021;137:e100–15. - 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 2019;29:1507-17. - Lin L, Ma H, Wang J, Guan H, Yang M, Tong X, 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 2019;26:409-16. - Havryliuk Y, Setton R, Carlow JJ, Shaktman BD. Symptomatic Fibroid Management: Systematic Review of the Literature. JSLS. 2017 Jul-Sep;21(3). pii: e2017.00041 - Criteria for CPT Category I and Category III codes. American Medical Association. https://www.ama-

#	Rationale
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2	The medical literature shows compelling and consistent beneficial outcomes treating women with symptomatic uterine fibroids with laparoscopic RFA (Acessa) and transcervical RFA (Sonata). The number of studies and study subjects is greater for Acessa however the Sonata procedure is well supported as well.Compared to UAE and L/S myomectomy, the laparoscopic RFA procedure, has similar short-term reintervention rates, symptom severity score improvement and QOL changes. Length of hospitalization and recovery were shorter in the subjects who underwent L/S RFA, although this may be explained in part by the protocol for L/S myomectomy patients to stay overnight. The primary limitation of the evidence is that very few studies provide outcome data for longer than 2 years of follow-up. However, the medical literature is sparse for long-term outcomes following myomectomy and UAE as well. In fact, short follow-up is a problem in the surgical literature across many specialties. The studies published to date enrolled symptomatic woman without excessively large fibroids, employed validated surveys to measure symptom improvement and reported verifiable, objective outcomes such as re-intervention rates. Most of the studies were conducted in the US. Many of the studies excluded women who desire future childbearing. However in the few studies that did report subsequent pregnancies, the outcomes were reassuring. There doesn't seem to be a compelling reason to exclude women who wish to conceive from having these procedures and the hope is they will be included in future studies.For the transcervical RFA procedure, the evidence comes from prospective single arm studies only. Although these studies lack a comparison group, the studies show few adverse events, improvement in heavy bleeding and low re-intervention rates. Data from the SAGE Registry, consisting of 500 subjects from 50 European sites, followed for 5 years will be extremely valuable to confirm the promising earlier results.In summary, there is evidence of clinically meaningful improvements in the net health outcomes of subjects who have undergone these two procedures. It is extremely important to have more treatment options for women with fibroids than we currently have. Many hospitals do not have gynecologic surgeons with the expertise to perform L/S myomectomies which relegates these women to undergo abdominal myomectomies or hysterectomies. Laparoscopic RFA may be a less complicated procedure to perform and thus should allow more gynecologists to be trained in the technique. I fully expect future studies will show less blood loss, shorter surgical time and less post-op pain compared to L/S or abdominal myomectomies.
3	It is important to take into account patient desires for management options and majority of patients desire uterine-sparing, least invasive procedures with minimal recovery time (PMID: 23891629). The cited data in the review of RFA does show lower reintervention rates and comparable symptom improvement and quality of life compared to UAE and myomectomy. Myomectomy recovery time is highly variable and in patients who desire improvement in symptoms with quicker recovery, RFA would afford a meaningful benefit.The use of laparoscopic or transcervical RFA allows for the shortest recovery period and time to return to work (PMID: 30253997, 29670382). This is a clinically meaningful outcome for patients when deciding which treatment to choose for fibroid management. Laparoscopic RF ablation in RCT showed shorter hospital stay, less intraoperative blood loss and greater number of fibroids treated particularly intramural fibroids (PMID: 24698202). While the cited published RCTs compare RFA to laparoscopic myomectomy (LM) in clinical practice this represents an incomplete comparison group. In clinical practice patients may not be candidates for the alternatives to RFA including laparoscopic myomectomy or UAE. Patients with intramural fibroids who would not otherwise be a candidate for laparoscopic myomectomy would benefit most from RFA, particularly if it allows avoidance of laparotomy. In addition many patients do not have access to surgeons with advanced laparoscopic suturing skills to perform laparoscopic myomectomy for intramural or multiple

#	Rationale
	fibroids and therefore their alternative to RFA is actually open myomectomy. Patients who do not accept blood products (i.e., Jehovah's Witness) would also have clinically meaningful improvement due to decreased blood loss with RFA compared to myomectomy.

Question 2.

Are RFA re-interventions appropriate after an initial RFA of uterine fibroids? If so, what criteria may guide appropriate time interval for RFA re-intervention and what would be the expected durability of this procedure? Please comment on benefits and harms of RFA re-intervention compared to re-intervention with myomectomy or other uterine sparing interventions.

#	Rationale
1	The data published thus far shows quite low re-intervention rates, however repeating the procedure may be necessary if new fibroids develop or the viable part of a fibroid enlarges. I believe repeating a laparoscopic or transcervical RFA would be appropriate if the patient had had at least a partial response to the initial procedure. Currently, there are no limitations on the number of times a gynecologist can perform a hysteroscopic, laparoscopic or abdominal myomectomy. For example, in my fibroid referral practice, I see patients who have undergone incomplete hysteroscopic myomectomies 3-5 times before before being referred for a 2nd opinion. Sometimes a two stage operation is planned for removal of a large submucosal fibroid. I expect gynecologists would exercise good judgment and not continue to perform a procedure that had failed to provide any relief. The harms from laparoscopic RFA re-intervention are likely to be significantly less than the harms from repeating a laparoscopic or abdominal myomectomy. In particular, repeat abdominal myomectomies are extremely challenging and ineffective procedures. If patients could have fibroids treated less invasively with laparoscopic RFA it could be extremely beneficial.
2	In Iversen et al, 40 out of the 60 patients (65%) included in the study did not undergo major reinterventions after lap RFA. Of the remaining patients, six underwent major reinterventions for reasons unrelated to myoma complaints. Overall, the major reintervention rate due to myoma-related symptoms was estimated to be 13.5% and 29.1% after 2-years and 5-years, respectively. These reinterventions were largely related to age, with patients <45 years of age having a major reintervention rate of 35% and 73.8% at 2-years and 5-years, respectively, and patients 45 years and less had a much lower major reintervention rate of 12% and 19% at 2-years and 5-years, respectively. Berman et al had similar findings with a 3-year reintervention rate of 11%. These rates are comparable to UAE - an already established and accepted management tool for symptomatic uterine fibroids - reintervention rates, which vary from 40%, 36%, and 50% after 5-years (Freed et al, Moss et al, Spies et al). These findings are also reflected similarly in a meta-analysis conducted by Lin et al, which found an overall lap RFA reintervention rate of 4.39%. Furthermore, a recently released assessment from the American Association of Gynecologist Laparoscopists (AAGL) found that in a review of available literature, rare major complications and reintervention rates for patients receiving lap RFA are low. Given the results of these studies assessing reintervention after lap RFA, rates are low for those likely to desire uterine preservation (45 years or younger) and are comparable to other uterine sparing interventions, such as UAE. References - Iversen H, Dueholm M. Radiofrequency Thermal Ablation for Uterine Myomas: Long-term Clinical Outcomes and Reinterventions. J Minim Invasive Gynecol. 2017 Sep-Oct;24(6):1020-1028. doi: 10.1016/j.jmig.2017.05.021. Epub 2017 Jun 27. PMID: 28662989. - Berman, JM, et al. Three-year outcome of the Halt trial: a prospective analysis of radiofrequency volumetric thermal ablation of myomas. J Minim Invasive Gynecol, 2014. 21(5), 767-774. - Lin L, Ma H, Wang J, Guan H, Yang M, Tong X, Zou Y. Quality of Life, Adverse Events, and Reintervention Outcomes after Laparoscopic Radiofrequency Ablation for Symptomatic Uterine Fibroids: A Meta-Analysis. J Minim Invasive Gynecol. 2019 Mar-Apr;26(3):409-416. doi: 10.1016/j.jmig.2018.09.772. Epub 2018 Sep 22. PMID: 30253997. - Kho KA et al. Systematic Review of Outcomes after Radiofrequency Ablation for Fibroids: An Aagl Practice Committee Evidence Review2021. 28(11): S23. - Freed MM, Spies JB. Uterine artery embolization for fibroids: a review of current outcomes. Semin Reprod Med. 2010;28(3):235-241. doi:10.1055/s-0030-1251480 - Moss JG, Cooper KG, Khaund A, et al. Randomised comparison of uterine artery embolisation (UAE) with surgical treatment in patients with symptomatic uterine fibroids (REST trial): 5-year results. BJOG. 2011;118(8):936-944. doi:10.1111/j.1471-0528.2011.02952.x

#	Rationale
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3	There is no data to draw upon regarding RFA re-intervention, however the cause for reintervention would need to be taken into account. Re-intervention due to poor initial response would not be appropriate. In contrast, reintervention due to growth of new symptomatic fibroids at a later time frame would be feasible. Compared to myomectomy with risk of adhesion formation, reintervention with laparoscopic RFA would pose less risk of complications, while maintaining expected benefit. Since the technology can be targeted to a designated area, there is no concern for overtreatment of adjacent tissue.

Question 3:
Please provide in the box below any comments you may wish to share about differences between the laparoscopic and transcervical approached to the use of RFA of uterine fibroids with evidence that demonstrates health outcomes you would like to highlight.

#	Rationale
1	ACOG believes that all approaches for RFA are similarly effective in reducing uterine fibroids and in improving quality of life metrics, with laparoscopic RFA being studied most rigorously. The location of the leiomyomata may lead to a clinical decision of one approach versus the other. For example, predominantly lower uterine segment or cervical leiomyomata, or those with a predominant submucosal location, may suggest a transcervical approach, whereas those fibroids with largely fundal or extramural components may suggest a laparoscopic approach. References- 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 2019;29:1507-17.
2	Although the data is more sparse for transcervical RFA, I believe this procedure fills a significant gap in our treatment options for women with fibroids. Currently, women with < 3 cm type 0 and type 1 fibroids can be treated quite effectively with hysteroscopic myomectomy. However, type 2 and type 3 fibroids are much more difficult to treat hysteroscopically. As a result, not infrequently, I need to perform a L/S myomectomy to remove fibroids in these locations because they are causing heavy periods or are interfering with embryo implantation in women trying to conceive. A laparoscopic myomectomy with a full thickness incision into the myometrium will then require future deliveries by C-section. If a transcervical RFA could be performed instead, women with these type 2 or type 3 fibroid, could have a less invasive procedure, with less post-op pain, shorter recovery times and eliminate the need for obligatory C-section deliveries.
3	The transcervical approach to RFA provides the least invasive approach for management of symptomatic fibroids given lack of any abdominal adhesions. In addition it offers treatment for a different patient population with FIGO type 2 and 3 fibroids which otherwise are not accessible through hysteroscopic or laparoscopic routes.

Question 4.
Would you agree that the following criteria for identifying individuals with symptomatic uterine fibroids for RFA treatment are clinically appropriate?
Women 18 and older when ALL of the following conditions are met:

- Evidence of uterine fibroids via ultrasound that are less than 10cm in diameter for Acessa or 7cm for Sonata, and
- Patient desires a uterine sparing treatment approach or is contraindicated for hysterectomy, and
- Patient has experienced any one of the following symptoms that are a direct result of the fibroid(s):
- Menorrhagia interferes with daily activities or causes anemia; or
- Pelvic pain or pressure, or
- Lower back pain; or
- Urinary symptoms (e.g., urinary frequency, urgency) related to compression of the bladder; or
- Gastrointestinal symptoms related to compression of the bowel (e.g., constipation, bloating); or
- Dyspareunia (painful or difficult sexual relations)

#	YES/NO	Rationale
1	YES	These criteria would encompass the patient population that would qualify for the lap RFA procedure in question. However, there is no accepted guideline on the size of leiomyoma that would indicate a patient for the procedure.
2	NO	I agree with the list of conditions except I would favor a lower cut off for fibroid size. Until there is data showing RFA can successful treat fibroids as large as 10 cm and 7 cm respectively, I would recommend an upper size limit of 7 cm for Acessa and 5 cm for Sonata. I agree that women desiring future childbearing should not be an excluded from laparoscopic or transcervical RFA procedures.
3	YES	The fibroid symptoms studies in RFA treatment are included above – anemia, bleeding and bulk symptoms. Identification of fibroids via ultrasound within the last year would be the minimum requirement. Some patients may require MRI to distinguish fibroids from adenomyosis or adenomyomas if there is any question on ultrasound. Other recommended criteria: 1- Normal endometrial biopsy / sampling for women > 45 years old with menorrhagia or irregular bleeding 2- Overall uterine size less than or equal to 16 weeks size (size cutoff used in most clinical studies)

Question 5.

Please provide in the box below any additional comments about the clinical context or specific clinical pathways for this topic and/or any key citations (including the PMID) with evidence that demonstrates health outcomes you would like to highlight.

#	Additional Comments
1	There are several components that further demonstrate the medical necessity of coverage lap RFA for those desiring uterine preservation. Firstly, the topic of uterine fibroids and their treatment is a considerable health equity issue. Uterine fibroids affect an estimated 26 million women in the US between the ages of 15 and 50 years, with Black women three times more likely to experience uterine fibroids compared to women of other racial groups. Ensuring equitable access to medically necessary treatment options is critical to providing quality care to all women suffering from uterine fibroids.Additionally, lap RFA is a cost-effective alternative for the treatment of uterine fibroids. Based on a 2010 dollars assessment, fibroids result in substantial healthcare expenditures, with estimated annual direct costs between $4.1 and $9.4 billion. Additionally, estimated lost work costs ranged from $1.55 to $17.2 billion. In totality, uterine fibroids were estimated to cost the US $5.9 to $34.4 billion annually. Compared to other uterine fibroid treatment options, lap RFA typically costs less than its counterparts including total hysterectomy, myomectomy, and uterine artery embolization. References - Cardozo ER, Clark AD, Banks NK, Henne MB, Stegmann BJ, Segars JH. The estimated annual cost of uterine leiomyomata in the United States. Am J Obstet Gynecol. 2012 Mar;206(3):211.e1-9. - Management of symptomatic uterine leiomyomas. ACOG Practice Bulletin No. 228. American College of Obstetricians and Gynecologists. Obstet Gynecol 2021;137:e100–15.
2	There may be a role for combining laparoscopic myomectomy with laparoscopic RFA in certain circumstance that would particularly benefit women with numerous fibroids. Specifically, a potential use of laparoscopic RFA would be to treat small fibroids that would otherwise be left in situ during a laparoscopic myomectomy or would require an abdominal myomectomy to remove. For example, when a woman has > 10 fibroids, I typically recommend an abdominal myomectomy because I can remove most, if not all, the fibroids this way. Alternatively, I can perform the myomectomy laparoscopically, removing the largest, "clinically significant" fibroids but leaving small fibroids in place. The choice is between a more invasive surgery (abdominal myomectomy) with removal of all the fibroids or a less invasive surgery (L/S myomectomy) with small fibroids remaining. If instead I could remove the bulky fibroids laparoscopically AND treat the small fibroids with laparoscopic RFA then the patient has the best possible outcome using the least invasive procedure.
3	It is important to highlight that while more data is needed on pregnancy outcomes after RFA – the existing data is promising and does not indicate adverse outcomes. This is a major contrast to UAE in which negative pregnancy outcomes have been seen and thus desire for future fertility is contraindicated.While not yet published – emerging data continues to suggest no increase in adverse pregnancy outcomes with RFA technology. An updated review of 46 pregnancies after RFA (8% pregnancy rate) had 35 full term pregnancies without adverse complications.DOI: https://doi.org/10.1016/j.jmig.2021.09.335

Question 6.
Is there any key evidence missing from the attached draft review of evidence that demonstrates clinically meaningful improvement in net health outcome? If YES, please share any relevant scientific citations of missing evidence (including the PMID).

#	YES / NO	Citations of Missing Evidence
1	YES	Please see questions above for relevant evidence context and reference list.
2	NO	
3	YES	Jacoby VL, Parvataneni R, Oberman E, Saberi NS, Varon S, Schembri M, Waetjen LE. Laparoscopic Radiofrequency Ablation of Uterine Leiomyomas: Clinical Outcomes during Early Adoption into Surgical Practice. J Minim Invasive Gynecol. 2020 May-Jun; 27(4): 915-925. PMID: 31376584. This study shows durable clinical improvement in symptoms and QOL improvement for patients undergoing the procedure by general gynecologists who were new to the technology. There were no intraoperative complications, conversion to laparotomy or major adverse events.

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
- Clinical findings (i.e., pertinent symptoms and duration)
- Comorbidities
- Reason procedure is preferable to alternatives
- Pertinent past procedural and surgical history
- Prior conservative treatments, duration, and response
- Treatment plan (i.e., surgical intervention)
- Consultation and medical clearance report(s), when applicable
- Pertinent radiology report(s) and interpretation (i.e., MRI, CT, US)
- Pertinent laboratory results

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency ***(Deleted code effective 1/1/2024)***
	58578	Unlisted laparoscopy procedure, uterus
	58580	Transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency ***(Code effective 1/1/2024)***
	58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency
	58999	Unlisted procedure, female genital system (nonobstetrical)
	76940	Ultrasound guidance for, and monitoring of, parenchymal tissue ablation
	76998	Ultrasonic guidance, intraoperative
	77022	Magnetic resonance imaging guidance for, and monitoring of, parenchymal tissue ablation
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
08/29/2014	BCBSA Medical Policy adoption
10/01/2016	Policy revision without position change
02/01/2017	Coding update
10/01/2017	Policy revision without position change
10/01/2018	Policy revision without position change
12/16/2019	Policy revision without position change
04/01/2020	Annual review. No change to policy statement.
11/01/2020	No change to policy statement. Literature review updated.
10/01/2021	Annual review. No change to policy statement.
06/01/2022	Annual review. Policy statement, guidelines and literature review updated. Policy title changed from Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids to current one.
04/01/2023	Annual review. Policy statement, guidelines and literature review updated.
03/01/2024	Coding update.
04/01/2024	Annual review. No change to policy statement. Policy guidelines and literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) 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 the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis 4.01.19 **Policy Statement:** I. 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: A. 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 B. 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]) (see Policy Guidelines) C. Individual has experienced at least **one** of the following symptoms that are a direct result of the fibroid(s): 1. Menorrhagia or other abnormal uterine bleeding that interferes with daily activities or causes anemia (see Policy Guidelines) 2. Pelvic pain or pressure 3. Urinary symptoms (e.g., urinary frequency, urgency) related to bulk compression of the bladder 4. Gastrointestinal symptoms related to bulk compression of the bowel (e.g., constipation, bloating) 5. Dyspareunia (painful or difficult sexual relations) II. 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, are considered **investigational**.	**Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis 4.01.19** **Policy Statement:** I. 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: A. 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 B. 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]) (see Policy Guidelines) C. Individual has experienced at least **one** of the following symptoms that are a direct result of the fibroid(s): 1. Menorrhagia or other abnormal uterine bleeding that interferes with daily activities or causes anemia (see Policy Guidelines) 2. Pelvic pain or pressure 3. Urinary symptoms (e.g., urinary frequency, urgency) related to bulk compression of the bladder 4. Gastrointestinal symptoms related to bulk compression of the bowel (e.g., constipation, bloating) 5. Dyspareunia (painful or difficult sexual relations) II. 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, are considered **investigational**.