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Laparoscopic, Percutaneous and Transcervical Techniques for Uterine Fibroid Myolysis

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Coverage

Laparoscopic or transcervical radiofrequency ablation (RFA) (e.g., Acessa®, Sonata®) as a treatment of symptomatic uterine fibroids **may be considered medically necessary** in individuals who:

- Have evidence of uterine fibroids via ultrasound;
- Desire 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**);
- Have experienced at least one of the following symptoms that are a direct result of the fibroid(s):
  - Menorrhagia or other abnormal uterine bleeding that interferes with daily activities or causes anemia (see **Policy Guidelines**);
  - Pelvic pain or pressure;

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

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 experimental, investigational and/or unproven.**

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 >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 ≤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 sub-serosal
	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.

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 (MRI)-guided laser ablation.

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 medical policy SUR701.015). 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.

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 Acessa Health in 2020. FDA product code: HFG.

In 2018, the Sonata® Sonography-Guided Transcervical Fibroid Ablation System (Gynsonics) was cleared for marketing by the FDA through the 510(k) process for diagnostic intrauterine imaging and transcervical 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, 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 policy (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

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 to 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 a technology, two domains were examined: the relevance and the quality and credibility. To be relevant, studies must represent one 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.

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 policy.

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 QOL 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 QOL 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 two days (range 0.5 to 6.0). No data were provided on length of stay after RFA.

Lin et al. (2019) conducted a meta-analysis of improvement in symptom severity, QOL, and reintervention after RFA. (8) The review included one RCT (interim analysis only with high loss to follow-up) and seven 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 QOL 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 QOL improved from 38.8 points before treatment to 83.3 points at 12 months (n=183). Reported reintervention 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).

Chen et al. (2024) conducted a systematic review to evaluate the efficacy of RFA for symptomatic fibroids. (12) The review included 30 studies: 3 RCTs, 1 nonrandomized comparative study, and 26 cohort studies. Meta-analysis was performed when at least 3 studies reported data for the same outcome. The results demonstrated reductions in symptom severity scores from baseline (52.5) to follow-up at 1 year (12.8), 2 years (16.7), 3 years (24.8), and 5 years (27.6) with the use of RFA. Additionally, RFA was associated with improvements in HRQOL scores, increasing from a baseline of 71.6 to 86 at 1 year, 88.3 at 2 years, 86.9 at 3 years, and 83.0 at 5 years.

Table 1. Characteristics of Systematic Reviews on RFA

Study	Dates	Trials	Participants	N	Design	Duration, mo.
Sandberg et al. (2018) (6)	2006-2016	45	Women with symptomatic uterine fibroids undergoing myomectomy, UAE, or laparoscopic RFA	17,789	Studies evaluating reintervention and QOL with consecutive enrollment and follow-up of ≥12 mo	11.2 – 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 QOL	>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)	12-36 mo
Arnreiter and Oppelt (2021) (10)	2011-2019	10	Women with symptomatic uterine fibroids undergoing transcervical RFA with the SONATA system	Range, 1-147	Studies that reported on myoma volume, patient-reported outcomes, surgical reinterventions, side effects, and safety during pregnancy and delivery	1 week - 64.4 mo

Chen et al. (2024) (12)	Up to Sept 2023	30	Women with symptomatic uterine fibroids undergoing transvaginal or transabdominal RFA	Range, 11 to 1216	Studies evaluating symptoms and QOL	3 mo - 5 years

mo: month; QOL: quality of life; RFA: radiofrequency ablation; UAE: uterine artery embolization. SONATA: sonography-guided transcervical ablation of uterine fibroids.

Table 2. Results of Systematic Reviews on RFA

Study	**Reintervention Risk (95% CI), %**			**Change in Symptom Severity Score (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 months*						
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				<0.001	<0.001	<0.001	<0.001	<0.001
Bradley et al. (2019) (9)								
Total Studies								
RFA (various)	4.2	11.5			-40		+39	
					<0.001		<0.001	
Arnreiter and Oppelt (2021) (10)								
Transcervical RFA				-55.1 (SD, 41.0)			277%	
Chen et al. (2024) (12)								
Total studies				11	3	2	14	3

RFA (various)				Total score estimate: 12.8 (7 to 18.6)	Total score estimate: 16.7 (1.2 to 32.3)	Total score estimate: 24.8 (19.3 to 30.2)	Total score estimate: 87.39 (83.7 to 92.1)	Total score estimate: 83.3 (78.5 to 88.2)

CI: confidence interval; QOL: quality of life; RFA: radiofrequency ablation; SD: standard deviation; UAE: uterine artery embolization.

Randomized Controlled Trials of Laparoscopic RFA

Studies of laparoscopic RFA include RCTs. One RCT evaluating laparoscopic RFA (Brucker et al., 2014) (13) 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. (14) 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. (15) 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. (16) 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 RFA

					Interventions	
Study	**Countries**	**Sites**	**Dates**	**Participants[a]**	**Active**	**Comparator**
Brucker et al. (2014) (13); Hahn et al. (2015) (17); Kramer et al. (2016) (18)	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) (14) (TRUST Canada)	Canada	Multiple	2012-2017	• ≥18 y • Menstruating • 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	RFA=23	LM=22
Yu et al. (2022) (16) (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	RFA=29	LM=27

				• Race or ethnicity: 26% to 48% White, 44% to 47% Black, 0% to 13% Asian, 3% to 7% Other, 3% to 7% Latino/ Hispanic		

LM: laparoscopic myomectomy; RFA: radiofrequency ablation; y: year; cm: centimeter; wk: weeks; TRUST: Treatment Results of Uterine Sparing Technologies.
[a] Key eligibility criteria.

Table 4. Summary of Key RCT Outcomes for Laparoscopic RFA

Study	**Primary Outcome**	**Secondary Outcomes**			
	Hospital LOS (SD), hours	**Mean SSS**		**Mean HRQOL**	
		12 mo	*24 mo*	*12 mo*	*24 mo*
Brucker et al. (2014) (13); Hahn et al. (2015) (17); Kramer et al. (2016) (18)	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	<0.001[b]	NS[c]	NS	NS	NS
Rattray et al. (2018) (14) (TRUST Canada)					
Laparoscopic RFA	6.7 (3.0)				
Laparoscopic myomectomy	9.9 (10.7)				
p	<.001				
Yu et al. (2022) (16) (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; RCT: randomized controlled trials; RFA: radiofrequency volumetric thermal ablation; SSS: Symptom Severity Score; SD: Standard Deviation; mo: months; 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 non-inferiority: 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, (13) 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 RFA (Acessa) group, there was an unplanned hospitalization due to unexplained vertigo and four 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) (17) (12-month outcomes) and by Kramer et al. (2016) (18) (12-month and 24-month outcomes). In addition to summary symptom and QOL 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 intention-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) (13); Hahn et al. (2015) (17); Kramer et al. (2016) (18)	4. Enrolled populations do not reflect relevant diversity.				1. Insufficient to determine reinterven-tion rates
Rattray et al. (2018) (14) (TRUST Canada)					
Yu et al. (2022) (16) (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. Clinically significant difference not prespecified; 6. Clinically 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) (13); Hahn et al. (2015) (17); Kramer et al. (2016) (18)				6. Not intent-to-treat	1. Power for secondary outcomes unclear	
Rattray et al. (2018) (14) (TRUST Canada)		1, 2, 3. No blinding				
Yu et al. (2022) (16) (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. (19) 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). (20) 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. (21) 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 QOL 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. (22) 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 symptom severity scores (SSS), HR-QoL, 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%. (23) 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), HR-QoL (p<.001), QOL (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. (24) 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 of 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. (25) 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, HR-QoL, 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). (26) 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 RFA

Study	Study Location	Participants	Treatment Delivery	Follow-up

Brolmann et al. (2016) (24) (FAST-EU)	7 community or academic gynecologists in EU and Mexico	50 women ≥28 years of age with heavy menstrual bleeding for a least 3 months and no desire to become pregnant	VizAblate transcervical RFA	12 mo
Miller et al. (2020) (22, 23) (SONATA)	24 community or academic gynecologists from 21 centers in the U.S. and Mexico	147 premenopausal women 25-50 years of age with symptomatic uterine fibroids (1-5 cm) with heavy menstrual bleeding and no desire to become pregnant	Sonata transcervical RFA	3 years
Christoffel et al. (2021) (26) (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; mo: month; RFA: radiofrequency ablation; SAGE: Transcervical Radiofrequency Ablation of Uterine Fibroids global Registry; SONATA: sonography-guided transcervical ablation of uterine fibroids; U.S.: United States.

Table 8. Summary of Single-Arm Study Results for Transcervical RFA

Study	Baseline	3 mo	12 mo	24 mo	36 mo
Brolmann et al. (2016) (24) (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)		
HR-QoL	34.3 (19.0)	76.4 (22.2)	80.7 (24.7)		
Surgical reintervention			4 (8%)		
Miller et al. (2020) (22, 23) (SONATA)					
n (%)	147			125 (85%)	105 (71%)
Symptom Severity Score (SD)	55 (19)	27 (19) p<.001		24 (18) p<0.001	22 (21) p<.001

HR-QoL (SD)	40 (21)	78 (22) p<.001		83 (19) p<0.001	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; HR-QoL: Health-related quality of life; FAST-EU: Fibroid Ablation Study EU; mo: month(s); RFA: radiofrequency ablation; SAGE: TranScervical Radiofrequency Ablation of Uterine Fibroids Global Registry; SD: standard deviation; SONATA: sonography-guided transcervical ablation of uterine fibroids.

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. (27) 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. (28) 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. (29) 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. (30) 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. In a follow-up study, Hansen-Lindner et al. (2024) reported on 89 pregnancies among 72 women, which included 55 deliveries (19 vaginal and 35 cesarean), 5 induced abortions, and 18 first-trimester spontaneous abortions. (31) Two patients contributed disproportionately to the rate of spontaneous abortions due to a history of recurrent miscarriage. No cases of uterine rupture or stillbirth were reported. There were 4 cases of postpartum hemorrhage.

Allen et al. (2024) conducted a prospective cohort study comparing pregnancy outcomes following laparoscopic RFA and myomectomy as part of the ULTRA trial. (32) Among 43 pregnancies (22 RFA, 21 myomectomy), miscarriage rates were similar: 40.9% (n=9) in the RFA group and 42.9% (n=9) in the myomectomy group (p=0.903). Live birth rates were also comparable, with 50.0% (n=11) in the RFA group and 57.1% (n=12) in the myomectomy group (p=0.661). However, all live births following myomectomy were delivered via cesarean section, whereas 45.5% of live births in the RFA group were delivered vaginally.

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 policy.

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 HR-QoL. The immediate follow-up would be a week for postoperative pain and recovery, and three to five 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. (33) 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. (34) Symptoms included pelvic pain, pressure, dyspareunia, and recurrent menorrhagia. The Nd:YAG laser was inserted into the fibroid multiple times (e.g., 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. (35) 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. (36, 37)

Section Summary: Laser or Bipolar Needles

The evidence base 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 policy.

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 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 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 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 HR-QoL. The immediate follow-up would be a week for postoperative pain and recovery, and three to five 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) (38) published a prospective pilot study with 14 patients, and Zupi et al. (2004) (39) presented their experience with 20 patients. (38, 39) 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. (40) 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 policy.

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 HR-QOL. 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). (41) 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 QOL 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) (41)	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; U.K.: United Kingdom; MRI: magnetic resonance imaging; y: year.

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) (41)				
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			0.02	0.06

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) (41)					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. Clinically significant difference not prespecified; 6. Clinically 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) (41)	1-4. Not randomized, inadequate	1-3. Not blinded		1.High loss to follow-up		

	control for selection bias					

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.

Summary of Evidence

For individuals who have symptomatic uterine fibroids who receive radiofrequency ablation (RFA), the evidence includes prospective cohorts, randomized controlled trials (RCTs), and systematic reviews. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The meta-analysis found low rates of reintervention with RFA and quality of life outcomes that were similar to uterine artery embolization and myomectomy at 12 months. Data on reintervention rates at 36 months were limited to 1 RCT and 1 cohort study with high loss to follow-up. No studies reported reintervention rates at 60 months. Two RCTs found that RFA was noninferior and one RCT found that RFA was superior to laparoscopic myomectomy on the primary outcome: length of hospitalization. A number of secondary outcomes were reported at 12 or 24 months in 2 RCTs, including symptoms and quality of life. One RCT found that both symptoms and quality of life were significantly better with myomectomy compared with RFA at 12 months. The procedure has faster recovery than myomectomy and provides a reduction in symptoms and improvement in quality of life in the short term. Recurrence and reintervention rates at longer follow-up are unknown. Well-designed comparative trials with longer follow-up are needed to determine the effect of RFA on health outcomes compared with other treatment options such as myomectomy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

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

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

Clinical Input From Physician Specialty Societies and Academic Medical Centers

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.

Practice Guidelines and Position Statements

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 (NICE)

In 2021, the NICE published an interventional procedures guidance on the use of transcervical ultrasound-guided RFA for symptomatic uterine fibroids. (42) 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, the NICE recommends that the procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this medical policy are listed in Table 13.

Table 13. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
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	Sept 2025
Unpublished			
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.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	58578, 58580, 58674, 58999, 76940, 76998, 77022, [Deleted 1/2024: 0404T]
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
01/01/2026	Document updated. The following changes were made to Coverage: Added the following: "Have evidence of uterine fibroids via ultrasound;" "Desire a uterine-sparing treatment approach or is ineligible for hysterectomy or other uterine-sparing alternatives to RFA"; other revisions without change to intent. References 12, 31, 32 added; others updated.
08/15/2024	Document updated with literature review. Coverage unchanged. Added references 1, 11, 15, 18-19, 27, and 29.
10/15/2023	Reviewed. No changes.
07/15/2022	Document updated with literature review. Coverage unchanged. The following references were added: 1-3, 10, 12, 13, 16, 18, 20, 21, 23, and 33. Title changed from: Laparoscopic, Percutaneous and Transcervical Techniques for the Myolysis of Uterine Fibroids.
01/01/2022	Reviewed. No changes.
11/15/2020	Document updated with literature review. The following change was made to Coverage: Medically necessary statement on ultrasound-guided radiofrequency ablation modified to conditionally cover transcervical technique (e.g., Sonata). Added references 2, 4-6, and 10-11.
07/01/2019	Document updated with literature review. Coverage unchanged. Added references 2, 3, 10-14.
12/01/2017	Reviewed. No changes.
12/01/2016	Document updated with literature review. Coverage unchanged.
01/01/2016	Document updated with literature review. Coverage has changed: "Transcervical" has been added to the following statement: Laparoscopic, percutaneous and transcervical techniques of myolysis as a treatment of uterine fibroids other than laparoscopic ultrasound-guided radiofrequency ablation (e.g., Acessa ™) are considered experimental, investigational and/or unproven, including Nd:Yag Lasers, bipolar electrodes, and supercooled cryoprobes. Title has been changed from: Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids.
10/01/2015	Reviewed. No changes.
10/15/2014	New policy. Coverage for laparoscopic ultrasound-guided radiofrequency ablation (e.g., Acessa™) for the treatment of uterine fibroids has changed to conditionally medically necessary when criteria are met. Laparoscopic and percutaneous techniques of myolysis as a treatment of uterine fibroids other

	than laparoscopic ultrasound-guided radiofrequency ablation (e.g., Acessa ™) are considered experimental, investigational and/or unproven. This topic was previously addressed on SUR701.014 Endoscopic, Arthroscopic, Laparoscopic and Thoracoscopic Surgery.