Medical Policy

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(See policy history boxes for previous effective dates)

Title: Myolysis of Uterine Fibroids using Laparoscopic, Percutaneous, or Transcervical Techniques

Description/Background

UTERINE FIBROIDS

Uterine fibroids, also known as leiomyomas, are among the most common conditions affecting women in the 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 2-3 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 treatment for symptom resolution. However, there is the potential for surgical complications and, in the case of hysterectomy, the uterus is not preserved. In addition, multiple myomectomies may be associated with longer operating time, postoperative febrile morbidity and development of pelvic adhesions. There has been long-standing research interest in developing minimally invasive alternatives for treating uterine fibroids, including procedures that retain the uterus and permit future childbearing. Treatment options include uterine artery embolization (see policy, “Uterine Artery Embolization” [retired]) and the transcutaneous procedure magnetic resonance imaging (MRI)-guided focused ultrasound therapy (see policy, “MRI-Guided Focused Ultrasound”). 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 multiple 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 MRI 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). FDA product code: HFG.

In 2018, the Sonata® Sonography-Guided Transcervical Fibroid Ablation System (Gynesonics, Inc., Redwood City, CA) was cleared for marketing by the FDA through the 510(k) process for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids (K173703). The Sonata System 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 not products specifically approved for the treatment of uterine fibroids.

Medical Policy Statement

Laparoscopic or transcervical ultrasound-guided radiofrequency ablation (e.g., Acessa™ or Sonata® System ™) for the treatment of uterine fibroids is established. It may be considered a useful therapeutic option when indicated.

Laparoscopic and percutaneous techniques of myolysis as a treatment of uterine fibroids other than laparoscopic ultrasound-guided radiofrequency ablation (e.g., Acessa™) and transcervical ultrasound-guided radiofrequency ablation (e.g., Sonata® System) are considered experimental/investigational; including Nd: YAG lasers, bipolar electrodes and cryomyolysis. There is insufficient published evidence to assess the safety and/or impact on health outcomes in the treatment of uterine fibroids.

Inclusionary and Exclusionary Guidelines

Inclusions:

Laparoscopic or transcervical ultrasound-guided radiofrequency ablation (e.g., Acessa™ or Sonata® System™)

Laparoscopic or transcervical ultrasound-guided radiofrequency ablation for the treatment of uterine fibroids may be indicated as an alternative to hysterectomy or myomectomy when the member has one or more of the following:

- Evidence of uterine fibroids via ultrasound that are less than 10cm in diameter for Acessa™ or 7cm for Sonata™, **and**
- Pre-menopausal state with symptomatic fibroids in members who want to avoid a hysterectomy, **or**
- Members who have contraindications to general anesthesia, **and**
- Members who have experienced any one of the following symptoms that are the direct result of the fibroid(s):
  - Severe menorrhagia causing anemia; **or**
  - Bulk-related symptoms (e.g., pelvic pain, pressure or discomfort, urinary symptoms related to compression of the ureter or bladder, and/or dyspareunia)

Exclusions:

Laparoscopic or transcervical ultrasound-guided radiofrequency ablation (e.g., Acessa™ or Sonata® System™) for all situations other than those specified above, and not limited to the conditions below:

- When there has been a diagnosis of cancer (or pre-cancerous lesions) anywhere in the pelvis, **or**
- In members who are diagnosed with or at risk for leiomyosarcoma, **or**
- In members with acute pelvic inflammatory disease, **or**
- In members with abnormal pap smear test results, **or**
- In members who are in post-menopausal state, **or**
- Pedunculated fibroid type 0 or type 7 for the Sonata® System™

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

58674 58580

Other codes (investigational, not medically necessary, etc.):

58578 58999

Rationale

Evidence reviews 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, 2 domains are 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 is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials 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 women 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 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 are 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.

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 (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 RFA compared with 3.6% for UAE and 1.1% for myomectomy. Symptom severity scores and quality of life scores were similar for the 3 treatments. Only one 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%; I2 = 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 mo follow-up) compared with 4.2% after myomectomy (6 studies, 12 to 52 mo 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 the 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%; I2=65.0%; 7 studies). Improvements in symptoms and QOL were maintained out to 24 months in three studies and out to 36 months in one 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.

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 any reintervention and quality of life with consecutive enrollment and follow-up of ≥12 mo	11.2-34.7
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)	12-36 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

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

Table 2. Results of Systematic Reviews on RFA

Study	Reintervention Risk (95% CI), %	Symptom Severity Score (95% CI)	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 (1.60−8.45)		-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	p<0.001	p<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%	

CI: confidence interval; QOL: quality of life; RFA: radiofrequency volumetric thermal ablation; SD: standard deviation; SSS: Symptom SeverityScore; 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; [5] 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.

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)[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) NCT015663783	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) 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% to48% 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 RFA

Study	Primary Outcome	Secondary Outcomes			
	Hospital LOS (SD), h[a]	Mean SSS		Mean HrQOL	
		12 mo	24 mo	12 mo	24 mo
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	<0.001[b]	*NS*[c]	*NS*	*NS*	*NS*
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 RFVTA no more than 10% longer than after laparoscopic myomectomy.
[c]Exact between-group p values were not reported

In the Brucker trial et al (2014)[12] trial, 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 4 hospitalizations as standard procedure because the patients also underwent adhesiolysis.

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 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)[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 limitations 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 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 limitations 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 was a prospective single arm study with 147 premenopausal women who had symptomatic uterine fibroids 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 symptom severity scores (SSS), health-related quality of life (HRQL), and EQ-5D. The cumulative rate of surgical intervention for heavy menstrual bleeding was 5.2% (95% confidence interval [CI] 2.5% to 10.6%). Follow-up is continuing through 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), HR-QoL (P<.001), quality of life (P<.001) work absenteeism (P<.001), and 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. 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. The Symptom Severity Score was obtained in all patients except for one

patient due to pregnancy. A clinically significant minimum 10 point reduction in the Symptom Severity Score 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, 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%.

Table 7. Summary of Single Arm Study Characteristics for Transcervical RFA

Study	Study Location	Participants	Treatment Delivery[1]	Follow-Up
Brolmann et al (2016)[23] FAST-EU	Seven 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(TM) transcervical RFA	12 mo
Miller et al (2019)[21]	Twenty-four Community or academic gynecologists from 21 centers in the US and Mexico	147 premenopausal women 25-50 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 500women ≥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 to25.0)

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. Case Series Results

Study	Baseline	3 mo	12 mo	24 mo
Brolmann et al (2016) [16] 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 (2019)[21,]				
n (%)	147			125 (85%)
Symptom Severity Score (SD)	55 (19)			24 (18) P<.001
HRQL (SD)	40 (21)			83 (19) P<.001
EQ-5D (SD)	0.72 (0.21)			0.89 (0.14) P<0.001
Surgical reintervention				5.5%

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

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 RFA, the investigators identified 20 pregnancies reported in 4 case series; the denominator (ie, the number of patients treated in these series) was not reported. Of the 20 pregnancies, seven were undesired and were electively terminated. For the remaining 13 pregnancies, there was one 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 (24vaginal, 20 cesarean) and 6 spontaneous abortions. Two delivery complications occurred (1 placenta previa, 1delayed 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 26full-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 20deliveries (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 an RCT comparing RFA with laparoscopic myomectomy have been published. The meta-analysis found low rates of reintervention with RFA and quality of life outcomes that were similar to myomectomy and UAE at 12 months. The RCT found that RFA was noninferior to laparoscopic myomectomy on the primary outcome (length of hospitalization). A number of secondary outcomes of the RCT were reported at 12 and 24 months, including symptoms and quality of life outcomes; none differed significantly between groups. Case series and prospective nonrandomized studies have also demonstrated safety and effectiveness. The procedure is associated with a reduction in symptoms and improvement in quality of life.

LASER OR BIPOLAR NEEDLES

Clinical Context and Therapy Purpose
The purpose of therapy with laser or bipolar needles in patients 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 o bipolar needles.

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 are 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.

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 with that produced by Nd:YAG laser. An earlier study by Goldfarb (1992), included 75 patients who presented with symptomatic fibroids 5 to10 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 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 base on the use of lasers or bipolar needles includes case series, small in size, and published in the 1990s. RCTs comparing laser and bipolar needles to alternative treatments for uterine fibroids and reporting health outcomes are needed.

CRYOMYOLYSIS

Clinical Context and Therapy Purpose
The purpose of cryomyolysis in patients 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 -180ºC 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 and practices are currently being used for managing uterine fibroids: medical management, UAE, myomectomy, and hysterectomy. Surgery, including hysterectomy and myomectomy are 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.

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 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 (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 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 patients 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 are 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.

REVIEW OF EVIDENCE

Nonrandomized Studies

No RCTs evaluating MRI-guided laser ablation were identified. A nonrandomized study by Hindley et al (2002) was identified (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 (ie, 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			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 (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 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 limitations 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]	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 limitations 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. There was incomplete data reporting, and self-reported outcomes were worse compared with a historical control group of women undergoing hysterectomy. RCTs comparing MRI-guided laser ablation with alternative treatments for uterine fibroids and reporting health outcomes are needed.

SUMMARY OF EVIDENCE

Various laparoscopic and percutaneous techniques for the myolysis of uterine fibroids have been proposed.

Data from a RCT and studies on ultrasound-guided radiofrequency ablation of uterine fibroids has shown that the procedure is well tolerated with shorter hospital stays resulting in high

patient satisfaction and improved quality of life. Three-year outcomes reported sustained relief from myoma symptoms and lower reintervention rates when compared with uterine artery embolization and myomectomy.

The body of evidence on the alternative laparoscopic (laser or bipolar needles, cryomyolysis), percutaneous (magnetic resonance imaging-guided laser ablation) and transcervical procedures is inadequate to permit conclusions regarding their impact on health outcomes. Data are needed from well-designed randomized controlled trials comparing the new technologies with surgery and/or other minimally invasive procedures. Moreover, the impact of these techniques on fertility need to be better understood, as it is hoped that laparoscopic and/or percutaneous myolysis procedures will preserve fertility.

SUPPLEMENTAL INFORMATION

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

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.

Ongoing and Unpublished Clinical Trials

Some currently 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			
NCT01563783[a]	The Trust (Treatment Results of Uterine Sparing Technologies) Study	260	Sep 2022
NCT03118037[a]	Transcervical Radiofrequency Ablation of Uterine Fibroids Global Registry (SAGE)	100	Dec 2025
NCT02163525[a]	Post Market TRUST - U.S.A. Study	114	Jun 2024
NCT02100904	Uterine Leiomyoma Treatment With Radiofrequency Ablation (ULTRA) Registry (ULTRA Registry)	800	Jan 2025
Unpublished			
NCT02260752	Patient-Centered Results for Uterine Fibroids (COMPARE-UF)	3,094	Sept 2020

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

Government Regulations

National:

There is no national coverage determination on this topic.

Local:

Wisconsin Physicians Insurance Service Corporation (WPS)
Local Coverage Determination (LCD): Ablative Therapy (L34527)
Original effective date 10/01/2015
Revision effective date 03/01/2016
Retirement date 04/01/2016

INDICATIONS:
Uterine leiomyoma, Percutaneous:

The use of RFA in symptomatic uterine leiomyomata is being studied in several centers. The issue of durability of the therapy, repeat procedures, and efficacy superior to other acceptable methods of therapy has not been determined. We have determined that RFA of uterine leiomyomata is not proven effective and thus not covered by Medicare.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Endometrial Ablation (BCN-only)
- MRI-Guided Focused Ultrasound (MRgFUS)
- Occlusion of Uterine Arteries Using Transcatheter Embolization - Retired

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through April 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/14	10/15/13	10/25/13	• Joint policy established
7/1/15	4/21/15	5/11/15	• Routine Maintenance • Updated References • Code 0336T – changed from E/I to Established • Added Codes: 77022 – to describe MRI imaging component 76940, 76998 – to describe ultrasound guidance • Medical Policy Statement updated • Added Inclusions/Exclusions for Laparoscopic ultrasound-guided radiofrequency ablation (e.g., Acessa™) • Coverage Determination updated
7/1/16	4/19/16	5/23/16	• Routine maintenance • Added CPT code 0404T for transcervical ablation of uterine fibroids • Removed codes 76940, 76998, 77022 • Added transcervical to policy title • Criteria and medical policy statement updated • Updated rationale, references and divergent statement
1/1/17	10/11/16	10/11/16	• Routine maintenance
7/1/17	4/18/17	4/18/17	• Routine maintenance • Deleted procedure code 0336T; added replacement code 58674
1/1/18	10/19/17	10/19/17	• Routine maintenance
1/1/19	10/16/18	10/16/18	• Routine maintenance

1/1/20	10/15/19		• Routine maintenance • Added FDA approval for Sonata® System; updated rationale and references
1/1/21	10/20/20		Routine maintenance Ref 2,6,10,11 added
9/1/21	6/15/21		• Added Sonata® System under the Medical Policy Statement as established. • Updated Inclusions and Exclusions for the Sonata® System • Ref 23-26 added
9/1/22	6/21/22		• Routine maintenance • References updated
9/1/23	6/13/23		• Routine maintenance • References updated • Vendor: N/A (ky)
5/1/24	2/20/24		• This policy is coming early as code update – informational to add code 58580 eff 1/1/24 per code update as EST. Code 0404T deleted eff 1/1/24. This new Category I code is being created to represent the transcervical incisionless ablation procedure for the treatment of uterine fibroids. The technology includes integrated, real-time intrauterine ultrasound guidance This policy will go back to its original date of June, 2024 JUMP. • Vendor: N/A (ky)

Next Review Date: 2nd Qtr, 2024

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: MYOLYSIS OF UTERINE FIBROIDS USING LAPAROSCOPIC, PERCUTANEOUS, OR TRANSCERVICAL TECHNIQUES

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Laparoscopic ultrasound-guided radiofrequency ablation (e.g., Acessa™), code 58674 and (Sonata ™), code 0404T - Covered, if criteria is met; see Inclusionary and Exclusionary Guidelines section Not Covered; All other techniques (laparoscopic, percutaneous, transcervical) of myolysis as a treatment of uterine fibroids (e.g., YAG lasers, bipolar electrodes, cryomyolysis,)
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.