Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids

Policy # 00445
Original Effective Date: 09/17/2014
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Occlusion of Uterine Arteries Using Transcatheter Embolization or Laparoscopic Occlusion to Treat Uterine Fibroids is addressed separately in medical policy 00130.

Note: Magnetic Resonance-Guided Focused Ultrasound is addressed separately in medical policy 00180.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers laparoscopic and percutaneous techniques of myolysis as a treatment of uterine fibroids are considered to be **investigational.***

Background/Overview

UTERINE FIBROIDS
Uterine fibroids, also known as leiomyomas, are among the most common conditions affecting women in their reproductive years; symptoms include menorrhagia, pelvic pressure, or pain.

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 myomectomy 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 ([UAE] see medical policy 00130) and the transcutaneous magnetic resonance imaging (MRI)–guided focused ultrasound therapy (see medical policy 00180). Various techniques to induce myolysis have also been studied including Nd:YAG lasers, bipolar electrodes, cryomyolysis, and radiofrequency ablation. With these techniques, an energy source is used to create areas of necrosis within uterine fibroids, reducing their volume and thus relieving symptoms. Early methods involved multiple insertions of probes into the fibroid, performed without imaging guidance. There were concerns about serosal injury and abdominopelvic adhesions with these techniques, possibly due to the multiple passes through the serosa needed to treat a single fibroid. Newer systems using radiofrequency energy do not require repetitive insertions of needle electrodes. Ultrasonography is used laparoscopically 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.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2012, the Acessa™‡ System (Acessa Health, formerly Halt Medical) was cleared for marketing by the U.S. 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 FDA (K132744). FDA product code: GEI.

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

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

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 (QOL), 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 (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.

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RADIOFREQUENCY VOLUMETRIC THERMAL ABLATION

Clinical Context and Therapy Purpose
The purpose of radiofrequency volumetric thermal ablation (RFVTA) in women who have uterine fibroids is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of RFVTA improve the net health outcome in women with uterine fibroids?

The following PICOTS were used to select literature to inform this review.

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

Interventions
The therapy being considered is RFVTA.

Comparators
The following therapies and practices are currently being used to make decisions about managing uterine fibroids: medical management, UAE, myomectomy, and hysterectomy.

Outcomes
The outcomes of interest are, complications, postoperative pain and recovery time, symptom resolution, need for reintervention, and health-related QOL.

Timing
Immediate follow-up (FU) would be a week for postoperative pain and recovery; and 3 to 5 years of FU would be needed to monitor for fibroid recurrence and retreatment.

Setting
RFVTA is administered is an inpatient or ambulatory surgery setting with treatment by a gynecologic surgeon.

Systematic Reviews
A systematic review and meta-analysis by Sandberg et al (2018) evaluated the risk of reintervention for hysterectomy and QOL after uterine-sparing interventions for fibroids (see Tables 1 and 2). Risk of reintervention at 12 months was 0.3% for RFVTA compared with 3.6% for UAE and 1.1% for myomectomy. Symptom severity and QOL scores were similar for the 3 treatments. Only 1 RFVTA study was identified on reintervention risk at 36 months; none was identified on reintervention risk at 60 months.

Table 1. Characteristics of Systematic Reviews on RFVTA

Study	Dates	Trials	Participants	N	Design	Duration, mo
Sandberg et al (2018)	2006-2016	45	Women with symptomatic uterine fibroids undergoing myomectomy, UAE, or RFVTA	17,789	Studies evaluating reintervention for hysterectomy and quality of life with consecutive enrollment and follow-up of ≥12 mo	11.2-34.7

RFVTA: radiofrequency volumetric thermal ablation; UAE: uterine artery embolization.

Table 2. Results of Systematic Reviews on RFVTA

Study	Reintervention Risk (95% CI), %			Symptom Severity Score at 12 mo (95% CI), %	QOL at 12 mo (95% CI), %
	At 12 Months	At 36 Months	At 60 Months		
Sandberg et al (2018)					
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)
RFVTA	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)

CI: confidence interval; QOL: quality of life; RFVTA: radiofrequency volumetric thermal ablation; UAE: uterine artery embolization.

Randomized Controlled Trials

One RCT evaluating RFVTA was included in the Sandberg et al (2018) systematic review, with Tables 3 and 4 describing trial characteristics and results.

Table 3. Summary of Key Randomized Controlled Trial Characteristics for RFVTA

					Interventions	
Study	Countries	Sites	Dates	Participants[a]	Active	Comparator
Brucker et al (2014)	Germany	1	2012-2013	• ≥18 y • Menstruating • Symptomatic uterine fibroids <10 cm • Uterine size ≤16 gestational wk • Desire uterine conservation • Not pregnant or lactating	RFVTA=26	LM=25

LM: laparoscopic myomectomy; RFVTA: radiofrequency volumetric thermal ablation.
[a] Key eligibility criteria.

Table 4. Summary of Key Randomized Controlled Trial Outcomes for RFVTA

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); Kramer et al (2016)	50	43[a]	43	43	43
RFVTA	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*

HRQOL: health-related quality of life; LOS: length of stay; RFVTA: radiofrequency volumetric thermal ablation; SSS: Symptom Severity Score.
[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 et al (2014) 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 RFVTA (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) (12-month outcomes) and by Kramer et al (2016) (12-month and 24-month outcomes). In addition to summary symptom and QOL measures displayed in Table 2, 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. Relevance Gaps

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Brucker et al (2014); Kramer et al (2016)					1. Insufficient to determine reintervention rates

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

Table 6. Study Design and Conduct Gaps

Study	Allocation[a]	Blinding[b]	Selective Reporting[d]	Data Completeness[e]	Power[d]	Statistical[f]
Brucker et al (2014); Kramer et al (2016)				6. Not intent-to-treat	1. Power for secondary outcomes unclear	

The evidence gaps 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.

Pregnancy Outcomes After RFVTA
Keltz et al (2017) published a systematic review of published literature on pregnancy outcomes after thermal ablation of uterine fibroids. For RFVTA, 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 delivered by cesarean section.

Section Summary: Radiofrequency Volumetric Thermal Ablation
A systematic review and an RCT comparing RFVTA with laparoscopic myomectomy (LM) have been published. The meta-analysis found low rates of reintervention with RFVTA and QOL outcomes that were similar to myomectomy and UAE at 12 months. Data on reintervention rates at 36 months was limited to a single study and no studies reported reintervention rates at 60 months. The RCT found that RFVTA was noninferior to LM 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 QOL outcomes; none differed significantly between groups. The RCT only had 43 patients in subgroup analyses at 12 and 24 months. Additional well-designed RCTs with longer FU are needed to determine the effect of RFVTA on health outcomes compared with other treatment options.

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 question addressed in this evidence review is: Does the use of laser or bipolar needles improve the net health outcome in women with uterine fibroids?

The following PICOTS were used to select literature to inform this review.

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

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Interventions
The therapy being considered is laser or bipolar needles.

Comparators
The following therapies and practices are currently being used to make decisions about managing uterine fibroids: medical management, UAE, myomectomy, and hysterectomy.

Outcomes
The outcomes of interest are, complications, postoperative pain and recovery time, symptom resolution, need for reintervention, and health-related QOL.

Timing
Immediate FU would be a week for postoperative pain and recovery; and 3 to 5 years of FU would be needed to monitor for fibroid recurrence and retreatment.

Setting
Laser or bipolar needles are administered is an inpatient or ambulatory surgery setting with treatment by a gynecologic surgeon.

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. 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. 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 FU, 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. 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.

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 patients who have uterine fibroids is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does cryomyolysis improve the net health outcome in women with uterine fibroids?

The following PICOTS were used to select literature to inform this review.

Patients
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 and practices are currently being used for managing uterine fibroids: medical management, UAE, myomectomy, and hysterectomy.

Outcomes
The outcomes of interest are, complications, postoperative pain and recovery time, symptom resolution, need for reintervention, and health-related QOL.

Timing
Immediate FU would be a week for postoperative pain and recovery; and 3 to 5 years of FU would be needed to monitor for fibroid recurrence and retreatment.

Setting
Cryomyolysis is administered is an inpatient or ambulatory surgery setting with treatment by a gynecologic surgeon.

Case Series
No controlled studies evaluating cryomyolysis were identified.

Two case series have been identified. Zreik et al (1998) published a prospective pilot study with 14 patients, and Zupi et al (2004) presented their experience with 20 patients. 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 FU of these patients. 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%. 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 patients who have uterine fibroids is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does MRI-guided laser ablation improve the net health outcome in women with uterine fibroids?

The following PICOTS were used to select literature to inform this review.
Patients
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 about managing uterine fibroids: medical management, UAE, myomectomy, and hysterectomy.

Outcomes
The outcomes of interest are, complications, postoperative pain and recovery time, resolution of symptoms, need for reintervention, and health-related QOL.

Timing
Immediate FU would be a week for postoperative pain and recovery; and 3 to 5 years of FU would be needed to monitor for fibroid recurrence and retreatment.

Setting
MRI-guided laser ablation is administered is an inpatient or ambulatory surgery setting with treatment by a gynecologic surgeon.

Nonrandomized Studies
No RCTs evaluating MRI-guided laser ablation were identified. A nonrandomized study by Hindley et al (2002) was identified (see Tables 7 and 8). 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 (MOQ) was significantly lower (i.e., worse outcomes) in those undergoing percutaneous myolysis. The QOL subscores did not differ statistically.

Table 7. Summary of Key Nonrandomized Trial Characteristics

Study	Type	Country	Participants	Treatment	Comparator	FU, y
Hindley et al (2002)	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 8. 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)				
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 gaps tables (see Tables 9 and 10) is to display notable gaps 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 9. Relevance Gaps

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Hindley et al (2002)	4. Self-selected population seeking to avoid open surgery				1. Not sufficient duration to assess reintervention

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 10. Study Design and Conduct Gaps

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

The evidence gaps 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: Magnetic Resonance Imaging–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 RFVTA, the evidence includes an RCT and systematic review. Relevant outcomes are symptoms, QOL, and treatment-related morbidity. The meta-analysis found low rates of reintervention with RFVTA and QOL outcomes that were similar to UAE and myomectomy at 12 months. Data on reintervention rates at 36 months were limited to 1 study and no studies reported reintervention rates at 60 months. The single RCT with a FU longer than 3 months found that RFVTA was noninferior to LM on the trial's primary outcome: length of hospitalization. A number of secondary outcomes were reported at 12 and 24 months, including symptoms and QOL. None of the secondary outcomes demonstrated significant between-group differences in a subgroup analysis of 43 patients. Additional well-designed RCTs with longer FU are needed to determine the effect of RFVTA on health outcomes compared with other treatment options. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have symptomatic uterine fibroids who receive laser or bipolar needles, the evidence includes case series. Relevant outcomes are symptoms, QOL, 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 the effects of the technology on health outcomes.

For individuals who have symptomatic uterine fibroids who receive cryomyolysis, the evidence includes case series. Relevant outcomes are symptoms, QOL, 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 the effects of the technology on health outcomes.

For individuals who have symptomatic uterine fibroids who receive MRI–guided laser ablation, the evidence includes a study with historical controls. Relevant outcomes are symptoms, QOL, 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 the effects of the technology on health outcomes.

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Policy History

Original Effective Date: 09/17/2014
Current Effective Date: 10/17/2018

09/04/2014	Medical Policy Committee review
09/17/2014	Medical Policy Implementation Committee approval. New policy.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015	Medical Policy Committee review
09/23/2015	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2016	Coding update
09/08/2016	Medical Policy Committee review
09/21/2016	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes and CPT coding update
10/05/2017	Medical Policy Committee review
10/18/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/04/2018	Medical Policy Committee review
10/17/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 10/2019

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids

Policy # 00445
Original Effective Date: 09/17/2014
Current Effective Date: 10/17/2018

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0404T, 58674, 76940, 77022
HCPCS	No codes
ICD-10 Diagnosis	D25.0-D25.9

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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