Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids


Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids. This is considered investigational.

When Policy Topic is covered
n/a

When Policy Topic is not covered
Laparoscopic and percutaneous techniques of myolysis as a treatment of uterine fibroids are considered investigational.

Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
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<tbody>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
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<tr>
<td>With uterine fibroids</td>
<td>• Radiofrequency volumetric thermal ablation</td>
<td>• Medical management</td>
<td>• Symptoms</td>
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<td>• Uterine artery embolization</td>
<td>• Quality of life</td>
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<td>• Myomectomy</td>
<td>• Treatment-related morbidity</td>
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<td>With uterine fibroids</td>
<td>• Laser and bipolar needles</td>
<td>• Medical management</td>
<td>• Symptoms</td>
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<tr>
<td></td>
<td></td>
<td>• Hysterectomy</td>
<td></td>
</tr>
</tbody>
</table>
A variety of minimally invasive treatments, alternatives to surgery, have been proposed for treatment of uterine fibroids. Among these approaches are laparoscopic and percutaneous techniques to induce myolysis, which includes Nd:YAG lasers, bipolar electrodes, supercooled cryoprobes, and ultrasonographically guided radiofrequency ablation (RFA).

For individuals who have uterine fibroids who receive RFVTA, the evidence includes 1 randomized controlled trial (RCT). Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The RCT found that RFVTA was noninferior to laparoscopic myomectomy on the study’s primary outcome, length of hospitalization. A number of secondary outcomes were reported at 12 and 24 months and there were no significant between-group differences on any of these. There were methodological limitations to this study eg, lack of intention-to-treat analysis, and the statistical hypotheses and analyses were not well-described. As a result, the validity of the reported results is decreased and no definitive conclusions can be made. Additional high-quality RCTs are needed to determine the effect of RFVTA on long-term health outcomes. Moreover, future studies should have a greater focus on fertility outcomes following RFVTA. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

For individuals who have uterine fibroids who receive cryomyolysis, the evidence includes case series. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. There were a small number of case series and sample sizes were small (≤20 patients). RCTs comparing cryomyolysis to alternative treatments for uterine fibroids are needed to adequately evaluate the safety and efficacy of this technology. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who have uterine fibroids who receive MRI-guided laser ablation, the evidence includes 1 case series. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. A single case series (N=66) is insufficient for evaluating the technology. RCTs comparing MRI-guided laser ablation to alternative treatments for uterine fibroids are needed to adequately evaluate the safety and efficacy of this technology. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Background**

**Uterine Fibroids**

Uterine fibroids 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 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 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 (see evidence review 4.01.11) and the transcutaneous procedure magnetic resonance imaging–guided focused ultrasound therapy (see separate policy).

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.¹ 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 magnetic resonance imaging guidance have also been reported.

**Regulatory Status**

In November 2012, the Acessa™ System (Acessa Health, Austin, TX, 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. The technology was previously approved in 2010, at which time it was called the Halt 2000GI™ Electrosurgical Radiofrequency Ablation System. The intended use of the Halt 2000GI™ system was for
percutaneous laparoscopic coagulation and ablation of soft tissue. Unlike FDA clearance of the Acessa™ System, the intended use statement for the Halt 2000GI™ system does not specifically mention the treatment of uterine fibroids. 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 (eg, Nd:YAG lasers, bipolar electrodes) have long-standing FDA approval, and there are not products specifically approved for treatment of uterine fibroids.

**Rationale**

This evidence review was created in July 2004 and has been updated regularly with searches of the MEDLINE database until it was archived in December 2009. In July 2013, the review returned to active status. The most recent literature update was performed through June 22, 2017.

Assessment of efficacy for a therapeutic intervention involves a determination of whether the intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition.

**Radiofrequency Volumetric Thermal Ablation**

**Randomized Controlled Trials**

One RCT evaluating radiofrequency volumetric thermal ablation (RFVTA) has been published and is described in Tables 1 and 2.

**Table 1. Summary of Key Randomized Controlled Trial Characteristics for RFVTA**

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brucker et al (2014)²</td>
<td>Germany</td>
<td>1</td>
<td>2012-2013</td>
<td>≥18 y  Menstruating  Symptomatic uterine fibroids  Fibroids &lt;10 cm  Uterine size ≤16 gestational wk  Desire uterine conservation  Not pregnant or lactating</td>
<td>RFVTA (n=26)  LM (m=25)</td>
</tr>
</tbody>
</table>
LM: laparoscopic myomectomy; RFVTA: radiofrequency volumetric thermal ablation.

Key eligibility criteria.

Table 2. Summary of Key Randomized Controlled Trial Outcomes for RFVTA

<table>
<thead>
<tr>
<th>Study (Year)</th>
<th>Primary Outcome</th>
<th>Secondary Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hospital LOS, h⁰</td>
<td>Mean SSS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12 mo</td>
</tr>
<tr>
<td>RFVTA</td>
<td>10.0 (SD=5.5)</td>
<td>24.7</td>
</tr>
<tr>
<td>Laparoscopic myomectomy</td>
<td>29.9 (SD=14.2)</td>
<td>26</td>
</tr>
<tr>
<td>p</td>
<td>&lt;0.001⁰</td>
<td>NS³</td>
</tr>
</tbody>
</table>

HRQOL: health-related quality of life; LOS: length of stay; RFVTA: radiofrequency volumetric thermal ablation; SSS: Symptom Severity Score.

⁰ Analyses at 12 and 24 months were per protocol and included 84% of randomized participants.

¹ Met criteria for noninferiority: hospital LOS after RFVTA no more than 10% longer than after LM.

³ Exact between-group p values were not reported.

In the Brucker 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 radiofrequency volumetric thermal ablation (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 in a 2015 publication by Hahn et al⁴ (12-month outcomes) and a 2016 publication by Kramer et al³ (12-month and 24-month outcomes). In addition to summary symptom and quality of life measures displayed in Table 2, the publications reported on 12 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). At 12 months, no participants reported four of the symptoms (dyspareunia, urinary retention, sleep disturbance, uterine pain) and there were no statistically significant between-group differences in the frequency of any of the remaining 8 symptoms (at the p<0.05 level). The most commonly reported symptom at 12 months (heavy menstrual bleeding) occurred in 7 (33%) of women in the RFVTA group and in 2 (9%) of women in the laparoscopic myomectomy group (p=0.069) after controlling for baseline bleeding. At 24 months, no participants reported urinary retention or “other” symptoms, and there were no statistically significant between-group differences in any of the 10 reported symptoms. The most commonly reported symptom at 24 months (dysmenorrhea) occurred in 8 (38%) patients in the RFVTA group and in 78 (32%) patients in the laparoscopic myomectomy group (p=0.67).

Limitations of the 12- and 24-month analyses 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.

**Observational Studies**

One prospective case series with longer term follow-up (ie, at least 2 years) was identified (see Tables 3-5).

### Table 3. Summary of Key Case Series Characteristics for RFVTA

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Location</th>
<th>N</th>
<th>Treatment</th>
<th>Follow-Up, mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chudnoff et al (2013)(^5); Berman et al (2014)(^6)</td>
<td>U.S. and Latin America</td>
<td>135</td>
<td>RFVTA</td>
<td>36(^a)</td>
</tr>
</tbody>
</table>

RFVTA: radiofrequency volumetric thermal ablation.

\(^a\) The 2 coprimary outcomes were reported at 12 months. Secondary outcomes are reported up to 36 months.

### Table 4. Summary of Key Case Series 12-Month Outcomes for RFVTA

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Treatment</th>
<th>At Least 50% Reduction in Volume of Menstrual Bleeding, N (%)(^a)</th>
<th>Surgical Reintervention Rate (% of Patients)(^a)</th>
<th>Mean QOL at 12 Months (% Change From Baseline)(^b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chudnoff et al (2013)(^5)</td>
<td>RFVTA</td>
<td>53 (40.2)</td>
<td>1 (0.7)</td>
<td>85.8 (15)</td>
</tr>
</tbody>
</table>

QOL: quality of life.

\(^a\) Coprimary efficacy outcome.

\(^b\) QOL measured using the EuroQol-5D instrument. N=123 at 12 months.

### Table 5. Summary of Key Case Series Reintervention Rates Up to 36 Months

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Outcome</th>
<th>Baseline to 12 Months</th>
<th>12-24 Months</th>
<th>24-36 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berman et al (2014)(^6)</td>
<td>Reintervention rate(^a)</td>
<td>1/123 (0.7)</td>
<td>6/129 (4.7)</td>
<td>7/118 (5.9)</td>
</tr>
</tbody>
</table>

\(^a\) Repeat interventions were: uterine artery embolization between baseline and 12 months; 2 myomectomies and 4 hysterectomies at 12-24 months and 7 hysterectomies at 24-36 months.

During the first 12 months of the Chudnoff and the Berman studies, device-related adverse events were reported in 5 (4%) women. No device-related adverse event was reported in the last 12 months of the study. The authors stated that quality of life variables improved from baseline to 36 months and that most of the improvement in quality of life occurred within 3 months of the procedure.

**Pregnancy Outcomes After RFVTA**

In 2017, Keltz et al published a systematic review of published literature on pregnancy outcomes after thermal ablation of uterine fibroids.\(^7\) For RFVTA, reviewers 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 delivered by cesarean section.

Section Summary: Radiofrequency Volumetric Thermal Ablation
One RCT comparing RFVTA with laparoscopic myomectomy has been published. That trial found RFVTA was noninferior to laparoscopic myomectomy on the primary outcome: length of hospitalization. Symptom resolution, reduction in fibroid number and size, quality of life, and treatment-related morbidity are key outcomes of interest. A number of secondary outcomes of the RCT were reported at 12 and 24 months, including symptoms and quality of life outcomes; none of these outcomes differed significantly between groups. The RCT had a relatively small sample size (N=50), and only included 43 (86%) patients in the analyses at 12 and 24 months. A prospective series found 3-year outcomes positive after RFVTA (ie, increase in quality of life and low reintervention rate). However, the series lacked a comparison group. Given the limitations in the RCT design and lack of significant benefit on clinically important outcomes, additional well-designed RCTs are needed to determine the effect of RFVTA on health outcomes compared with other treatment options.

Laser and Bipolar Needles
Several case series were identified, most published in the 1990s. For example, in 1995 Goldfarb reported 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 with 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 (eg, 75 to 100 punctures to coagulate a 5-cm fibroid). Based on an assessment by endovaginal ultrasound, the fibroids regressed in size and, after 6 to 14 months of follow-up, the size remained stable. No patient experienced significant complications. In 1993, Nisolle et al reported on a case series of 48 women offered myolysis instead of myomectomy if they had completed childbearing. Although the report stated that 28 of the 48 had more than 2 fibroids, it is not clear if all fibroids were treated in each patient, and, if not, how treated fibroids were selected. The authors reported that maximal decrease in fibroid size had occurred by 6 months. However, there was no report of associated patient symptoms.

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 and Bipolar Needles
Only case series are available, and they had small sample sizes and were published in the 1990s. RCTs comparing laser and bipolar needles with alternative treatments for uterine fibroids and reporting health outcomes are needed.
Cryomyolysis
Cryomyolysis entails inserting a -180°C cryoprobe into the center of a fibroid, creating an “iceball” within the fibroid. Several freeze/thaw cycles are typically used, and the process may not be standardized. No controlled studies evaluating cryomyolysis were identified. A few case series have been published. In 1998, Zreik et al published a prospective pilot study with 14 patients, and in 2004, Zupi et al presented their experience with 20 patients. In both case series, the authors reported that patients had symptom resolution. In the Zreik series, patients were given a gonadotropin-releasing hormone agonist before the procedure to reduce the size of the fibroid. Cryomyolysis maintained or slightly reduced the post-gonadotropin-releasing hormone uterine size. In contrast, in the Zupi study, gonadotropin-releasing hormone was not used, and cryomyolysis was associated with a 25% reduction in fibroid size. In 2005, Zupi et al reported on 1-year follow-up of these patients. Mean shrinkage in fibroid size continued until 9 months after surgery, to a mean volume reduction of 60%. Patients reported the absence of symptoms. Interpretation of these studies is limited due to their small sample sizes and lack of comparison groups.

Section Summary: Cryomyolysis
Several small case series are available. 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
No controlled studies evaluating magnetic resonance imaging–guided laser ablation were identified. One case series was identified (see Tables 6 and 7). Findings of the case series were compared with a historical control group of 43 women undergoing hysterectomy (details were not provided on where or when these women were treated). 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, but the quality of life subscores were similar.

Table 6. Summary of Key Case Series Characteristics for MRI-Guided Laser Ablation

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Location</th>
<th>N</th>
<th>Treatment</th>
<th>Follow-Up, y</th>
</tr>
</thead>
</table>

MRI: magnetic resonance imaging.

Table 7. Summary of Key Case Series Results for MRI-Guided Laser Ablation

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Treatment</th>
<th>Mean Fibroid Volume Reduction, %</th>
<th>Mean MOQ Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hindley et al (2002)</td>
<td>MRI-guided laser ablation</td>
<td>-31 (3 mo)a</td>
<td>51.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 41 (1 y)b</td>
<td></td>
</tr>
</tbody>
</table>
MRI: magnetic resonance imaging; MOQ: Menorrhagia Outcomes Questionnaire.

In the 47 (71%) patients with follow-up MRI scans at 3 months.

In the 24 (36%) patients with follow-up MRI scans at 1 year.

**Section Summary: Magnetic Resonance Imaging–Guided Laser Ablation**

A single case series 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 percutaneous laser ablation with alternative treatments for uterine fibroids and reporting health outcomes are needed.

**Summary of Evidence**

For individuals who have uterine fibroids who receive RFVTA, the evidence includes an RCT. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The RCT found that RFVTA was noninferior to laparoscopic myomectomy on the trial’s primary outcome: length of hospitalization. A number of secondary outcomes were reported at 12 and 24 months, including the clinically relevant outcomes (symptoms and quality of life), none of which demonstrated significant between-group differences. The RCT had a relatively small sample size (N=50), and only included 43 (86%) patients in 12- and 24-month analyses. A prospective case series with 3 years of follow-up reported positive outcomes (eg, increase in quality of life and low reintervention rate). Given the limitations in the RCT design and lack of significant benefit on clinically important outcomes, additional well-designed RCTs 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 uterine fibroids who receive laser or bipolar needles, the evidence includes case series. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The case series were published in the 1990s, and the procedures used then may not reflect current practice. RCTs comparing laser or bipolar needles with alternative treatments for uterine fibroids are needed to evaluate the safety and efficacy of this technology adequately. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

For individuals who have uterine fibroids who receive magnetic resonance imaging–guided laser ablation, the evidence includes a case series. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. A single case series (N=66) is insufficient for evaluating the technology. RCTs comparing magnetic resonance imaging–guided laser ablation 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.

**Supplemental Information**

**Practice Guidelines and Position Statements**

**Society of Obstetricians and Gynecologists of Canada**

In 2015, the Society of Obstetricians and Gynecologists of Canada published clinical guidelines on the management of uterine leiomyomas.\(^\text{17}\) The guidelines included the following summary statements:

- “Of the conservative interventional treatments currently available, uterine artery embolization has the longest track record and has been shown to be effective in properly selected patients.”
- “Newer focused energy delivery methods are promising but lack long-term data.”

**American College of Obstetricians and Gynecologists**

In 2016, the American College of Obstetricians and Gynecologists reaffirmed its 2008 Practice Bulletin on alternatives to hysterectomy in the management of leiomyomas.\(^\text{18,19}\) Recommendations based on good and consistent scientific evidence were that abdominal myomectomy is a safe and effective treatment for women with symptomatic leiomyomas and that uterine artery embolization is a safe and effective option for appropriately selected women who want to retain their uteri. The bulletin contained no recommendations on myolysis using laparoscopic or percutaneous techniques.

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

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

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this evidence review are listed in Table 8.

**Table 8. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
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<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01750008*</td>
<td>Laparoscopic Uterine Sparing Techniques Outcomes and Reinterventions (LUSTOR)</td>
<td>50</td>
<td>Sep 2018</td>
</tr>
<tr>
<td>NCT02100904</td>
<td>Uterine Leiomyoma Treatment With Radiofrequency Ablation (ULTRA) Registry (ULTRA Registry)</td>
<td>100</td>
<td>Jun 2019</td>
</tr>
</tbody>
</table>
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NCT02260752  Patient Centered Results for Uterine Fibroids (COMPARE-UF)  10,000  Sep 2019

NCT02228174a  Sonography Guided Transcervical Ablation of Uterine Fibroids (SONATA)  147  Oct 2019

NCT02163525a  Post Market TRUST - U.S.A. Study  300  Dec 2022

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

References

**Billing Coding/Physician Documentation Information**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0336T</td>
<td>Laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency (code deleted 12/31/16)</td>
</tr>
<tr>
<td>58578</td>
<td>Unlisted laparoscopy procedure, uterus</td>
</tr>
<tr>
<td>58674</td>
<td>Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency (new code 1/1/2017)</td>
</tr>
<tr>
<td>58999</td>
<td>Unlisted procedure, female genital system (nonobstetrical)</td>
</tr>
<tr>
<td>76940</td>
<td>Ultrasound guidance for, and monitoring of, parenchymal tissue ablation</td>
</tr>
<tr>
<td>76998</td>
<td>Ultrasonic guidance, intraoperative</td>
</tr>
<tr>
<td>77022</td>
<td>Magnetic resonance guidance for, and monitoring of, parenchymal tissue ablation</td>
</tr>
</tbody>
</table>

**ICD-10 Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>D25.0-</td>
<td>Leiomyoma of uterus, code range</td>
</tr>
<tr>
<td>D25.9</td>
<td></td>
</tr>
</tbody>
</table>

0336T: Laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency

This code is not to be reported with codes 76998 and 0071T.

There is no specific CPT code for laparoscopic or percutaneous lysis of uterine fibroids. The following codes might be used for a laparoscopic procedure:

58578: Unlisted laparoscopy procedure, uterus
58999: Unlisted procedure, female genital system (nonobstetrical)

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

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

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

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

Effective in 2017, there is a category I CPT code for radiofrequency ablation of uterine fibroids:
58674: Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency.

Prior to 2017, there was a category III CPT code:

0336T: Laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency

In November 2014, the U.S. Food and Drug Administration (FDA) published a safety communication on laparoscopic power morcellators used for myomectomy and hysterectomy in most women. (Morcellators are not otherwise addressed herein). FDA recommended that manufacturers of these devices include in their product labels a boxed safety warning and wording on contraindications (see http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm393809.htm).

Additional Policy Key Words
N/A

Policy Implementation/Update Information
9/1/15  New Policy, considered investigational.
9/1/16  No policy statement changes.
9/1/17  No policy statement changes.
9/1/18  No policy statement changes.

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