Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids

Policy Number: 4.01.19  Last Review: 9/2017
Origination: 9/2015  Next Review: 9/2018

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>
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<td>Individuals:</td>
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<td>▪ With uterine</td>
<td>Interventions</td>
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<td>Relevant outcomes include:</td>
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<td>fibroids</td>
<td>of interest</td>
<td>Medical management</td>
<td>Symptoms</td>
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<td>Uterine artery embolization</td>
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<td>▪ Radiofrequency volumetric thermal ablation</td>
<td>Myomectomy</td>
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<td>▪ With uterine fibroids</td>
<td>▪ Laser and bipolar needles</td>
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<td>Symptoms</td>
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<td>▪ With uterine fibroids</td>
<td>▪ Cryomyolysis</td>
<td>Medical management</td>
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<td>Quality of life</td>
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<td></td>
<td>Treatment-related morbidity</td>
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</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 are one of the most common conditions affecting women in the reproductive years; symptoms include menorrhagia, pelvic pressure, or pain. 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, in the case of multiple uterine fibroids, myomectomy can be a time-consuming procedure.

There has been longstanding research interest in developing minimally invasive alternatives for treating uterine fibroids, including procedures that retain the uterus and allow for future childbearing. Treatment options include uterine artery embolization, addressed in a separate policy and the transcutaneous procedure magnetic resonance imaging (MRI)–guided focused ultrasound therapy, addressed in a separate policy. Various techniques to induce myolysis have also been studied including Nd:YAG lasers, bipolar electrodes, cryomyolysis, and radiofrequency ablation. An energy source is used to create areas of necrosis within uterine fibroids, reducing their volume and thus relieving symptoms. Early methods involved the insertion of probes multiple times into the fibroid and were 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 multiple 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.

**Rationale**

This evidence review was originally created in July 2004 and was updated regularly with searches of the MEDLINE database until it was archived in December 2009. In July 2013, the review returned to active status. Most recently, the literature was reviewed through July 8, 2016.

**Laparoscopic Procedures**

**Radiofrequency Volumetric Thermal Ablation**

In 2014, Brucker et al in Germany published a single-center industry-sponsored RCT comparing radiofrequency volumetric thermal ablation (RFVTA) with the
Acessa system (Halt Medical) to laparoscopic myomectomy. The study included 51 premenopausal women at least 18 years old with symptomatic uterine fibroids less than 10 cm in any diameter and a uterine size of less than 17 weeks of gestation. Pregnancy and lactation were exclusion criteria. Prior to randomization, all participants underwent laparoscopic ultrasound mapping. Data on 50 of the 51 women were analyzed. The primary study outcome, mean (SD) time to hospital discharge, was 10.0 (5.5) hours in the RFVTA group and 29.9 (14.2) hours in the myomectomy group. The criteria for noninferiority, no more than 10% longer hospital stay with RFVTA than laparoscopic myomectomy, were met at a significance level of p< 0.001. 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 Acessa group, there was 1 unplanned hospitalization due to unexplained vertigo and 4 hospitalizations as standard procedure because the patients underwent adhesiolysis in addition to RFVTA.

Secondary outcomes of the RCT were reported in a 2015 publication by Hahn et al (12-month outcomes) and a 2016 publication by Kramer et al (24-month outcomes). Analysis was per protocol and 43 (84%) of 51 randomized participants were available for both the 12- and 24-month analyses. Each publication reported on 12 symptoms: heavy menstrual bleeding, increased abdominal gait, 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 4 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 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%) in the RFVTA group and 78 (32%) in the laparoscopic myomectomy group (p=0.67). Patients were also assessed using several validated questionnaires eg, the Uterine Fibroid Symptom Severity scale. There were no statistically significant between-group differences on any of these questionnaires at either 12 or 24 months. In addition, the authors described pregnancy outcomes. Three patients in the RFVTA group conceived and these all resulted in delivery of a healthy neonate; the number of women who desired to become pregnant was not reported. Limitations of the 12- and 24-month analyses include that they were not done by intention to treat and that secondary study hypotheses and statistical analyses were not clearly described. The RCT had a relatively small sample size and thus may have been underpowered to detect clinically meaningful differences in secondary outcomes, so these results do not rule out potential differences between the treatments.
In addition to the RCT, several uncontrolled case series with longer term follow-up (ie, at least 2 years) were identified. In 2013, Chudnoff et al published a prospective industry-funded multicenter study. It included 135 premenopausal women at least 25 years-old with symptomatic uterine fibroids, a uterine size of 14 weeks of gestation or less, and 6 or fewer treatable fibroids, with no single fibroid larger than 7 cm. In addition, women desired to preserve their uteri but not to have children in the future. RFVTA was conducted using the Acessa system. According to the study protocol, most fibroids less than 1 cm in diameter were not treated. The primary efficacy outcomes were change in the volume of menstrual bleeding and the surgical reintervention rate after 12 months. A total of 127 (94%) of 135 women completed the study. From baseline to 12 months, 53 (42%) of 127 women (95% confidence interval, 32% to 49%) experienced at least a 50% reduction in the volume of menstrual bleeding. Most women (104/127 [82%]) experienced a decrease in menstrual bleeding at 12 months. Only 1 woman underwent a surgical reintervention through 12 months (this woman had been lost to follow-up and was not included in the other efficacy analyses). Three-year outcomes were reported by Berman et al in 2014. A total of 104 (77%) of the 135 women who participated in the study were evaluable at 3 years. Fourteen women underwent reintervention over the 3 years to treat uterine fibroid symptoms. Eleven women had hysterectomies, 2 had myomectomies, and 1 had uterine artery embolization. Bleeding outcomes were not reported for the cohort at 3 years, but 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 in the 3 months following the procedure.

A large retrospective case series was published by Yin et al in 2015. The study was conducted in China and used Chinese gynecologic radiofrequency ablation devices. It included 1216 consecutive patients treated at a single hospital over a 10-year period. All fibroids were less than 6 cm in size and mean diameter was 4.5 cm (range, 3.1-6.0 cm). Mean follow-up time was 36.5 months. Among the 476 premenopausal women, the mean reduction in myoma diameter was 2.7 cm at 6 months, 2.4 cm at 12 months, and 2.2 cm at 24 months. Among the 740 peri- or postmenopausal women, mean reduction was 3.3 cm at 6 months, 2.3 cm at 12 months, and 2.3 cm at 24 months. Myoma diameter was significantly lower at each of these time points posttreatment compared with pretreatment. In the premenopausal subgroup, the proportion of women with dysmenorrhea decreased from 43.7% at baseline to 7.6% at 12 months and to 6.7% at 24 months; rates were significantly lower after treatment.

Section Summary: Radiofrequency Volumetric Thermal Ablation
One RCT comparing RFVTA and laparoscopic myomectomy has been published. The study found that RFVTA was noninferior to laparoscopic myomectomy on the 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 methodologic limitations, such as the analyses were per protocol and there were substantial missing data at 12 and 24 months, and the trial may not have had adequate power to detect differences in
clinical outcomes. Additional well designed RCTs are needed to determine the effect of RFVTA on long-term health outcomes.

**Laser and Bipolar Needles**

Several case series were identified and most of these were published in the 1990s. For example, in 1995 Goldfarb et al reported the outcomes of 300 women with symptomatic fibroids no larger than 10 cm who underwent myolysis using either Nd:YAG or bipolar needles. (8) 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. Another study by Goldfarb et al, published in 1992, included 75 patients who presented with symptomatic fibroids 5 to 10 cm in diameter. (9) 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 were used 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. In 1993, Nisolle et al reported on a case series of 48 women who were apparently offered myolysis instead of myomectomy if they had completed childbearing. Although the report states 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 the treated fibroids were selected. (10) The authors reported that maximal decrease in fibroid size had occurred by 6 months. However, there is no report of associated patient symptoms.

Several authors have reported pelvic adhesions as a complication, 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. (11,12)

**Section Summary: Laser and Bipolar Needles**

Only case series were available and most were published in the 1990s. RCTs comparing laser and bipolar needles to alternative treatments for uterine fibroids and reporting health outcomes are needed.

**Cryomyolysis**

Cryomyolysis is a technique in which a cryoprobe is inserted into the center of a fibroid. Freezing temperatures of -180°C create an “iceball” within the fibroid. Several freeze/thaw cycles are typically used. In 1998, Zreik et al published a prospective pilot study with 14 patients, and in in 2004, Zupi et al presented their experience with 20 patients. (13,14) In both of these small case series, the authors reported that patients had symptom resolution. In the Zreik study, patients were given a gonadotropin-releasing hormone (GnRH) agonist before the procedure to reduce the size of the fibroid. Cryomyolysis maintained or slightly reduced the post-GnRH uterine size. In contrast, in the Zupi study, GnRH was not used, and cryomyolysis was associated with a 25% reduction in fibroid size. In 2005, Zupi et al reported the 1-year follow-up of these patients. (15) Mean shrinkage in fibroid size continued until 9 months after surgery, to a mean volume reduction of 60%. Patients reported absence of symptoms. Interpretation of these studies is limited due to their small size and lack of a comparison group.
Section Summary: Cryomyolysis
Only several small case series were available. RCTs comparing laser and bipolar needles to alternative treatments for uterine fibroids and reporting health outcomes are needed.

Percutaneous Procedures

Magnetic Resonance Imaging–Guided Laser Ablation
In 2002, Hindley et al reported on a case series of 66 patients with symptomatic fibroids who were treated with magnetic resonance imaging (MRI)–guided percutaneous Nd:YAG laser myolysis. Outcome measures included assessment of fibroid size and responses to a menorrhagia questionnaire. The mean reduction in fibroid size was 31%. Compared with a historical control group of women undergoing hysterectomy, the total outcome score was less in those undergoing percutaneous myolysis, but the quality-of-life score was similar. Although not entirely clear, it appears that treatment was targeted to only the largest fibroid in each patient. The study did not provide details on the number and location of fibroids.

Section Summary: Magnetic Resonance Imaging–Guided Laser Ablation
Only 1 case series was identified. RCTs comparing laser and bipolar needles to alternative treatments for uterine fibroids and reporting health outcomes are needed.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this evidence review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
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<tr>
<td>NCT01563783a</td>
<td>The Trust (Treatment Results of Uterine Sparing Technologies) Study</td>
<td>260</td>
<td>Dec 2020</td>
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</table>

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

Summary of Evidence
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
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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 a clinical practice guideline on management of uterine leiomyomas.(17) The guideline included the summary following 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 2014, the American College of Obstetricians and Gynecologists reaffirmed a 2008 Practice Bulletin titled Alternatives to Hysterectomy in the Management of Leiomyomas.(18) Recommendations based on good and consistent scientific evidence are that abdominal myomectomy is a safe and effective treatment of
women with symptomatic leiomyomas and that uterine artery embolization is a safe and effective option for appropriately selected women who wish to retain their uteri. The bulletin contains no recommendations regarding myolysis utilizing laparoscopic or percutaneous techniques.

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**References:**


Billing Coding/Physician Documentation Information

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<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>
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<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>
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<td>58999</td>
<td>Unlisted procedure, female genital system (nonobstetrical)</td>
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<tr>
<td>76940</td>
<td>Ultrasound guidance for, and monitoring of, parenchymal tissue ablation</td>
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<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

- D25.0-D25.9: Leiomyoma of uterus, code range

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.

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.