A variety of minimally invasive treatments, alternatives to surgery, have been proposed for the 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.

Related Policies
- MRI-Guided Focused Ultrasound for the Treatment of Uterine Fibroids and Other Tumors
- Occlusion of Uterine Arteries Using Transcatheter Embolization

Policy
Laparoscopic and percutaneous techniques of myolysis as a treatment of uterine fibroids are considered investigational.

Policy Guidelines
There is a category III CPT code effective 01/01/14*:
- **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.

The following codes might be used for a laparoscopic procedure:
- **58578**: Unlisted laparoscopy procedure, uterus
- **58999**: Unlisted procedure, female genital system

For percutaneous procedures, the following code would likely be used to describe the MRI imaging component of the procedure
- **77022**: Magnetic resonance guidance for, and monitoring of, visceral tissue ablation

For ultrasound guidance, one of the following codes might be used:
- **76940**: Ultrasound guidance for and monitoring of, parenchymal tissue ablation
Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Rationale

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 Blue Shield of California Medical Policy: Occlusion of Uterine Arteries Using Transcatheter Embolization and the transcatheter and transcutaneous procedure magnetic resonance imaging (MRI)-guided focused ultrasound therapy (MRgFUS), addressed in Blue Shield of California Medical Policy: MRI-Guided Focused Ultrasound for the Treatment of Uterine Fibroids and Other Tumors. 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. (1) 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.

Regulatory Status

In November 2012, the Acessa™ System (Halt Medical, Brentwood, CA) was cleared for marketing by the U.S. Food and Drug Administration (FDA). The device is indicated for percutaneous laparoscopic coagulation and ablation of soft tissue. Treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance is one of the listed indications. The technology was previously approved in 2010, at which time it was called the Halt 2000GI™ Electrosurgical Radiofrequency Ablation System (Halt Medical, Brentwood, CA). The intended use of the Halt 2000GI™ system was for percutaneous
Medical Policy


Rationale

Randomized controlled trials (RCTs), which minimize selection bias and confounding, are the optimal study design for evaluating the safety and efficacy of a new medical intervention. Only 1 RCT comparing a laparoscopic and percutaneous myolysis technique with another uterine fibroid treatment (i.e., surgical methods or noninvasive procedures such as uterine artery embolization) was identified in literature searches. The RCT evaluated laparoscopic radiofrequency ablation and is described next.

The remainder of the literature consists of uncontrolled case series.

Laparoscopic Procedures

Ultrasound-Guided Radiofrequency Ablation

In 2014, Brucker et al. in Germany published an industry-sponsored RCT comparing radiofrequency ablation 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 time to hospital discharge (SD), was 10.0 (5.5) hours in the radiofrequency ablation group and 29.9 (14.2) hours in the myomectomy group. The criteria for noninferiority was met at a significance level of p less than 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 radiofrequency ablation. The study did not report outcomes beyond the perioperative period.

In addition to the RCT, several uncontrolled case series were identified. Data on the largest series was initially published in 2013 by Chudnoff et al. This industry-funded study was prospective and multicenter (9 sites in the U.S., 2 sites in Latin America). This study 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 uter i but not to have children in the future. Radiofrequency thermal ablation 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 of 135 women (94%) completed the study. From baseline to 12 months, 53 of 127 women (42%; 95% confidence interval, 32% to 49%) experienced at least a 50% reduction in the volume of menstrual bleeding. Most women (104 of 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 of the 135 women who participated in the study (77%) 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. The main limitation of the study was lack of a control or comparison group.

Other, smaller case series have also been published. For example, in 2011 Garza Leal et al. in Mexico reported on 31 women with symptomatic uterine fibroids who underwent ultrasound-guided radiofrequency ablation using the Halt 2000 system. Women wanted to retain their uteri but did not desire future pregnancies. Primary outcome measures included the frequency of adverse events, symptom reduction, reintervention rate, and scores on the Uterine Fibroid Symptom and Quality-of-Life (UFSQOL) questionnaire. Scores on the UFSQOL had a potential range of 0 to 100, with a lower symptom score indicating fewer symptoms and a higher quality-of-life score. None of the patients underwent another procedure related to uterine fibroid treatment during the follow-up period. Twenty-nine women (94%) completed 6 months of follow-up and 19 (61%) completed 12 months of follow-up. Seven of 31 women (23%) reported adverse events. These included 4 cases of abdominal pain after the procedure, 2 urinary tract infections, and 1 case of an abdominal wall vascular injury. At 6 months, the mean symptom score decreased by 72% and the mean quality of life score increased by 91%. Exact numbers were not reported. At baseline, 25 of 31 women (81%) reported heavy or very heavy menstrual bleeding. At 6 months, this was reported by 2 of 29 women (7%).

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. 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. Symptoms included pelvic pain, pressure, dyspareunia, and recurrent menorrhagia. The Nd:YAG laser was inserted into the fibroid multiple times; for example, 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. 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.

Cryomyolysis

Cryomyolysis is a technique in which a cryoprobe is inserted into the center of a fibroid. Freezing temperatures of -180° Centigrade create an “iceball” within the fibroid. Several freeze/thaw cycles are typically used. In 1998, Žeik et al. published a prospective pilot study with 14 patients, and in 2004, Župi et al. presented their experience with 20 patients. In both of these small case series, the authors reported that patients had symptom resolution. In the Žeik 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. (13) 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.

**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. (14) 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.

**Ongoing Clinical Trials**

Randomized controlled trials:

**Post Market TRUST (Treatment Results of Uterine Sparing Technologies) Study** (NCT01563783)(15): This industry-sponsored RCT is comparing global fibroid ablation, abdominal or laparoscopic myomectomy, and uterine artery embolization. The study is enrolling women who are at least 18 years old and menstruating, have symptomatic uterine fibroids, have a uterine size of no more than 16 weeks’ gestation, have fibroids less than 10 cm in any diameter and who desire uterine conservation. The primary outcomes are the relative costs of the procedures and adverse event rates in the 3 months following the procedures. Estimated enrollment is 260 women and the expected completion date is December 2019.

Case series:

**Uterine Leiomyoma Treatment With Radiofrequency Ablation (ULTRA) (NCT01840124)(16):** This single-arm uncontrolled study plans to include 100 women with symptomatic uterine fibroids who will be recruited from 5 sites in the University of California Fibroid Network. Patients will be treated with the Acessa™ system and will be followed for 3 years. The primary outcome is change in fibroid-related symptoms and a secondary outcome is the pregnancy rate after fibroid treatment. The estimated study completion date is June 2017.

**Fibroid Ablation Study - Large Fibroids (FAST-L) (NCT01539187)(17):** The single-arm uncontrolled study is being conducted at a number of sites outside of the U.S. (i.e., Mexico, the Netherlands, UK). It aims to enroll 48 women age 28 and older with a history of excessive bleeding for at least 3 months and at least 1 fibroid with a maximum diameter between 5 cm and 10 cm. Patients will be treated with the VizAblate™ ultrasound-guided radiofrequency ablation system and followed for 3 months. (VizAblate has not been cleared by the FDA). The primary outcome is the change in fibroid perfused volume. The estimated completion date is June 2015.

**Summary**

Various laparoscopic and percutaneous techniques for the myolysis of uterine fibroids have been proposed. Data on these procedures are inadequate to permit conclusions regarding their impact on health outcomes. Only 1 RCT has been published, comparing
radiofrequency ablation to laparoscopic myomectomy. Outcome reporting in this trial was limited to the perioperative period; longer term outcomes were not reported. The remainder of the evidence base consists of uncontrolled case series, mainly with small sample sizes. Data are needed from well-designed RCTs 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. However, the published articles on myolysis techniques primarily include women who do not desire future childbearing, and there is a lack of studies reporting successful pregnancies after treatment with these techniques. Because of these deficiencies in the published evidence, laparoscopic and percutaneous techniques of myolysis as a treatment of uterine fibroids are considered investigational.

**Practice Guidelines and Position Statements**

In 2012, 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**

Laparoscopic and percutaneous techniques for the myolysis of uterine fibroids is not a preventive service.

**References**


**Documentation Required for Clinical Review**

- No records required

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

IE

The following services are considered investigational and therefore not covered for any indication.
<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>0336T</td>
<td>Laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency</td>
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<td>HCPC</td>
<td>None</td>
<td></td>
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<tr>
<td>ICD-9 Procedure</td>
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**Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
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<tbody>
<tr>
<td>8/29/2014</td>
<td>BCBSA Medical Policy adoption</td>
<td>Medical Policy Committee</td>
</tr>
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</table>

**Definitions of Decision Determinations**

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements**
This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.