Corporate Medical Policy

Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids

File Name:	laparoscopic_and_percutaneous_techniques_for_the_myolysis_of_uterine_fibroids
Origination:	8/2013
Last CAP Review:	9/2018
Next CAP Review:	9/2019
Last Review:	9/2018

Description of Procedure or Service

Uterine fibroids are one of the most common conditions affecting individuals 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 (UAE) and the transcutaneous procedure magnetic resonance imaging (MRI)-guided focused ultrasound therapy (MRgFUS). 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.

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). Percutaneous laparoscopic coagulation and ablation of soft tissue and 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 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 treatment of uterine fibroids.

Cryoablation is a surgical procedure that uses previously approved and available cryoablation systems; and as a surgical procedure, it is not subject to relation by the FDA. Other products addressed in this review (YAG lasers, biopolar electrodes) have long-standing FDA approval, and there are not products specifically approved for treatment of uterine fibroids.

Related Policies and Guidelines
MRI-Guided Focused Ultrasound (MRgFUS)

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.*

Policy

Laparoscopic and percutaneous techniques of myolysis as a treatment of uterine fibroids are considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids are covered

Not applicable.

When Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids are not covered

Laparoscopic and percutaneous techniques of myolysis as a treatment of uterine fibroids are considered investigational for all applications.

Policy Guidelines

For individuals who have uterine fibroids who receive radiofrequency volumetric thermal ablation (RFVTA), the evidence includes 1 randomized controlled trial (RCT) and meta-analysis. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The meta-analysis found low rates of reintervention with RFVTA and quality of life outcomes that were similar to myomectomy and uterine artery embolization at 12 months. Data on reintervention rates at 36 months was limited to one study and there were no studies that reported reintervention rates at 60 months. The one RCT with follow-up longer than 3 months 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 symptoms and quality of life. None of the secondary outcomes demonstrated significant between-group differences with this sample of 43 patients. Additional well-designed RCTs with longer follow-up 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 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. Among the few case series, 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 a study with historical controls. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. A single study with historical controls is insufficient for evaluating the technology. RCTs comparing MRI-guided laser ablation with 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: *58674*

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 in this policy). 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).

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

American College of Obstetricians and Gynecologists (ACOG). Alternatives to hysterectomy in the management of leiomyomas. ACOG practice bulletin; no. 96. Available online at: www.guideline.gov. Last accessed August, 2013.

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.19, 7/11/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.19, 7/10/2014

American College of Obstetricians and Gynecologists (ACOG). Alternatives to hysterectomy in the management of leiomyomas. ACOG practice bulletin; no. 96. Available online at: www.guideline.gov. Last accessed September 2014.

Specialty Matched Consultant Advisory Panel 9/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.19, 7/9/2015

Specialty Matched Consultant Advisory Panel 9/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.19, 8/11/2016

American College of Obstetricians and Gynecologists (ACOG). Alternatives to hysterectomy in the management of leiomyomas. ACOG practice bulletin No. 96. 2008, reaffirmed 2014; http://www.acog.org/-/media/List-ofTitles/PBListOfTitles.pdf.

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.19, 8/10/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.19, 8/9/2018

Policy Implementation/Update Information

10/1/13 New policy developed. Laparoscopic and percutaneous techniques of myolysis as a treatment of uterine fibroids are considered investigational for all applications. Medical Director review. Notification given 10/1/13 for policy effective date 12/10/13. (sk)

10/28/14 References added. Policy Guidelines updated. Senior Medical Director review. Specialty Matched Consultant Advisory Panel review – 9/30/2014. No change to Policy statement. (sk)

9/1/15 Reference added. Information added to the Billing/Coding section regarding the FDA safety communication on laparoscopic power morcellators published in November 2014. (sk)

10/30/15 Specialty Matched Consultant Advisory Panel review – 9/30/2015. (sk)

12/30/15 Code 0404T added to Billing/Coding section. (sk)

2/29/16 Deleted code 0404T from Billing/Coding section. (an)

11/22/16 Specialty Matched Consultant Advisory Panel review 9/28/2016. Policy Guidelines updated. Added references. (an)

12/30/16 For 2017 coding update, code 0336T deleted and replaced with 58674 in Billing/Coding section. (an)

10/13/17 Reference added. Specialty Matched Consultant Advisory Panel review 9/27/2017. No change to policy statement. (an)

10/12/18 Policy Guidelines updated. Reference added. Specialty Matched Consultant Advisory Panel review 10/3/2018. No change to policy statement. (an)