Corporate Medical Policy

Ablative Techniques for the Myolysis of Uterine Fibroids

File Name:	ablative_techniques_for_the_myolysis_of_uterine_fibroids
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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 and hysteroscopically 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.

In August 2018, the Sonata® System received FDA clearance for marketing. This device is intended for ultrasound guided transcervical treatment of symptomatic uterine fibroids without incisions.

Ablative Techniques for the Myolysis 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, bipolar 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

BCBSNC will provide coverage for ablative techniques of myolysis as a treatment of uterine fibroids when it is considered to be medically necessary because the medical criteria and guidelines listed below are met.

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 Ablative Techniques for the Myolysis of Uterine Fibroids are covered

BCBSNC will provide coverage for ultra-sound guided radiofrequency ablation using Acessa™ or Sonata® when the following criteria are met:

1. For Acessa laparoscopic ultra-sound guided radiofrequency ablation, the Individual is eligible for and enrolled in the ULTRA Registry (see Policy Guidelines).
    - ULTRA Registry eligibility criteria are defined as women age 21 years or older who plan to undergo laparoscopic radiofrequency ablation(RFA), Acessa™ for treatment of uterine fibroids.

    OR

    For Sonata™ transcervical ultra-sound guided radiofrequency ablation, the Individual is eligible for and enrolled in the ATRIUM Registry (See Policy Guidelines).
    - ATRIUM Registry eligibility criteria are defined as women age 18 years or older who plan to undergo transcervical RFA, Sonata™ for treatment of uterine fibroids.

    AND

2. Individual has persistence of one or more symptoms directly attributable to uterine fibroids:
    - Excessive uterine bleeding as evidenced by either profuse or prolonged bleeding, or anemia due to acute or chronic blood loss; or,
    - Pelvic discomfort caused by myomata, manifesting as acute severe pain, chronic lower abdominal pain, dyspareunia, low back pressure or bladder pressure with urinary frequency not due to urinary tract infection.

When Ablative Techniques for the Myolysis of Uterine Fibroids are not covered

Laparoscopic ultra-sound guided radiofrequency ablation using Acessa™ is considered investigational for myomata with intracavitary or subserosal locations (FIGO Types 0,1, or 7). [See Policy Guidelines.]

Transcervical sonography-guided radiofrequency ablation using Sonata® outside the ATRIUM Registry is considered investigational.

All other ablative techniques for the myolysis as a treatment of uterine fibroids, including laser ablation and cryomyolysis, are considered investigational.

Policy Guidelines

ULTRA Registry
The Uterine Leiomyoma Treatment With Radiofrequency Ablation (ULTRA) Registry is a nationwide observational arm of the ULTRA trial (Clinicaltrials.gov, NCT02100904) to evaluate long-term safety and efficacy of laparoscopic radiofrequency ablation of uterine fibroids using the Acessa procedure™ (Acessa Health). Planned registry enrollment is 200 patients, with a completion date of June 2022. Patients will be followed in a 3 year prospective study conducted by University of California San Francisco (UCSF), but the ablation surgery will be performed by the patient's own gynecologist. Women are invited to partipate if they plan to undergo laparoscopic radiofrequency ablation (Acessa) in the United States. Eligibility criteria include patient age 21 years or older who are planning to undergo RF ablation (Acessa) for treatment of uterine fibroids, able to give informed consent and enrolled at contract clinical site prior to RF ablation treatment. Primary outcome measure is change in fibroid-related symptoms after the Acessa procedure (baseline to 3 years) based on standard questionnaire. Secondary outcome measures include rate of reintervention for recurrent fibroid symptoms following Acessa procedure (baseline to 6 weeks), operative complications (baseline to 6 weeks) and pregnancy rate after Acessa.

The PALM-COEIN International Federation of Gynecology and Obstetrics (FIGO) classification system for causes of abnormal uterine bleeding includes the category of leiomyoma with subclassification for intramural, subserosal, submucosal and transmural lesions. Intracavitary lesions are attached to the endometrium by a narrow stalk and are classified as type 0, whereas types 1 and 2 require a portion of the lesion to be intramural—with type 1 being less than 50% and type 2 at least 50%. The type 3 lesions are totally extracavitary but abut the endometrium. Type 4 lesions are intramural leiomyomas that are entirely within the myometrium, with no extension to the endometrial surface ortotheserosa. Subserosal (types5–7) leiomyomas represent the mirror image of the submucosal leiomyomas—with type 5 being at least 50% intramural, type 6 being less than 50% intramural, and Type 7 being attached to the serosa by a stalk. Classification of lesions that are transmural would be categorized by their relationship to both the endometrial and the serosal surfaces. The endometrial relationship would be noted first, with the serosal relationship second (e.g.2-3). An additional category, Type 8, is reserved for leiomyomas that do not relate to the myometrium at all, and would include cervical lesions, those that exist in the round or broad ligaments without direct attachment to the uterus, and other so-called "parasitic" lesions (Munro, Critchley, Broder, & Fraser, 2011).

Evidence summary
For individuals who have uterine fibroids who receive laparoscopic radiofrequency (RFA), the evidence includes 1 very small randomized controlled trial (RCT) and systematic review and meta-analysis. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The meta-analysis found low rates of reintervention with RFA 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 RCT at 3 months follow-up found that RFA 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. Although well-designed RCTs with longer follow-up to determine the effect of laparoscopic RFA on health outcomes compared with other treatment options are preferred, the current evidence is evolving. Ongoing patient participation in prospective registries could potentially address the gaps in the evidence and the effects of the technology on health outcomes.

The pivotal trial for laparoscopic RFA to determine safety and efficacy of RFA for symptomatic uterine fibroids excluded patients with pedunculated intracavitary or subserosal myomata. (Berman 2014)

Atrium Registry
For individuals who have uterine fibroids who receive transcervical sonography-guided radiofrequency ablation (RFA) using Sonata®, the evidence includes single-arm studies, the largest of which reported 3-year outcomes. Although the three-year outcome data reported significantly improved symptom severity scores, comparative effectiveness data for this type of treatment has not been published, and randomized controlled trials with larger patient populations are needed to adequately evaluate the long term efficacy of this technology. Ongoing patient participation in prospective registries could potentially address the gaps in the evidence and the effects of the technology on health outcomes; currently no ongoing registry exists for Sonata® in the United States. The ATRIUM registry will attempt to fill this evidence gap. Patients will be followed in a 3 year prospective study conducted by Atrium Health of Charlotte, North Carolina. Women are invited to participate if they plan to undergo transcervical radiofrequency ablation(RFA), Sonata™, at Atrium Health. Eligibility criteria include patient age 18 years or older who are planning to undergo transcervical RFA for treatment of uterine fibroids, able to give informed consent, and enrolled prior to RFA treatment. The number of concurrent fibroid procedures if any will be collected. The primary outcome measure is change in fibroid-related symptoms after the Sonata™ procedure (baseline to 3 years) based on a standard questionnaire. Secondary outcome measures include rate of reintervention for recurrent fibroid symptoms following the Sonata procedure (baseline to 3 years), operative complications (baseline to 6 weeks), and pregnancy rate after Sonata. Exclusion criteria include diagnosis of cancer or precancerous lesions anywhere in the pelvis, a diagnosis of or high risk for leiomyosarcoma, currently pregnant, or active pelvic inflammatory disease.

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, 0404T*

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.

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American College of Obstetricians and Gynecologists (ACOG).Practice Bulletin No. 228, MANAGEMENT OF SYMPTOMATIC UTERINE LEIOMYOMAS, OBSTETRICS & GYNECOLOGY: JUNE 2021 - VOLUME 137 - ISSUE 6 - P E100-E115.

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Medical Director review 9/2021

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.19, 9/2020

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)

10/15/19 Specialty Matched Consultant Advisory Panel review 9/18/2019. No change to policy statement. (eel)

02/25/20 Added "Laparoscopic ultra-sound guided radiofrequency ablation using Acessa™ is considered investigational for myomata with intracavitary or subserosal locations (FIGO Types 0,1, or 7). [See Policy Guidelines.]" to When not covered section. All coverage criteria newly added to When covered section. Policy guidelines and references updated. (eel)

03/10/20 Policy guidelines updated. No change to policy statement. (eel)

07/14/20 Corrected grammatical and spelling errors. Added Sonata statement for clarity in When not covered section. Description section updated. Added 0404T to coding section. (eel)

10/27/20 Specialty Matched Consultant Advisory Panel review 9/29/2020. References added. Policy title changed from "**Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids**" to "**Ablative Techniques for the Myolysis of Uterine Fibroids**". Policy statement updated from "laparoscopic and percutaneous" to "ablative" to match title change. Policy guidelines updated. No change to policy intent. (eel)

08/24/21 Added coverage Atrium registry for transcervical ultrasound guided radiofrequency ablation, "For Sonata™ transcervical ultra-sound guided radiofrequency ablation, the Individual is eligible for and enrolled in the ATRIUM Registry…." Policy Guidelines and References also updated. (mfm)

10/1/21 References updated. Specialty Matched Consultant Advisory Panel review 9/2021. Medical Director review 9/2021. No change to Policy statement. (jd/tt)