Corporate Medical Policy

Ablative Techniques for the Myolysis of Uterine Fibroids

File Name: ablative_techniques_for_the_myolysis_of_uterine_fibroids
Origination: 8/2013
Last Review: 3/2024

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 2012, the Acessa™ System (Acessa Health, 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. In 2014, the ultrasound guidance system received marketing clearance from the FDA. In 2018, the third-generation Acessa™ ProVu System® was cleared for marketing by the FDA through the 510(k) process for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. Hologic acquired Accessa Health in 2020.

In 2018, the Sonata® Sonography-Guided Transcervical Fibroid Ablation System (Gynesonics) was cleared for marketing by the FDA through the 510(k) process for diagnostic intrauterine imaging and transcervical radiofrequency ablation as treatment of symptomatic uterine fibroids (K173703). The Sonata System 2.1 received marketing clearance in 2020 (K193516) and the Sonata System 2.2 received marketing clearance in 2021 (K211535). The Sonata system was previously known as Vizablate. FDA product codes: KNF, ITX, and IYO.

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

Blue Cross NC will provide coverage for laparoscopic ultrasound guided radiofrequency ablation (Acessa) or transcervical ultrasound guided radiofrequency ablation (Sonata) when all the following criteria are met:

1. Age 18 years of age or older; AND

2. The individual has persistence of one or more symptoms attributable to uterine fibroids such as:
    a. Excessive uterine bleeding as evidenced by either profuse or prolonged bleeding;
    b. Anemia due to acute or chronic blood loss;
    c. 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 a urinary tract infection; AND

3. The individual has no contraindications to the procedure to include:
    a. a diagnosis of cancer or precancerous lesions anywhere in the pelvis
    b. a diagnosis of or high risk for leiomyosarcoma
    c. currently pregnant
    d. active pelvic inflammatory disease
    e. pedunculated or cervical fibroids (FIGO type 7 or 8)*

    *The presence of a pedunculated fibroid does not invalidate the use of the procedure for other fibroids.

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

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

Policy Guidelines

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).

For individuals who have symptomatic uterine fibroids who receive radiofrequency ablation (RFA), the evidence includes prospective cohorts, randomized controlled trials (RCTs), and systematic reviews. 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 uterine artery embolization and myomectomy at 12 months. Data on reintervention rates at 36 months were limited to 1 RCT and 1 cohort study with high loss to follow-up. No studies reported reintervention rates at 60 months. Two RCTs found that RFA was noninferior and one RCT found that RFA was superior to laparoscopic myomectomy on the primary outcome: length of hospitalization. A number of secondary outcomes were reported at 12 or 24 months in 2 RCTs, including symptoms and quality of life. One RCT found that both symptoms and quality of life were significantly better with myomectomy compared with RFA at 12 months. The procedure has faster recovery than myomectomy, and provides a reduction in symptoms and improvement in quality of life in the short term. Recurrence and reintervention rates at longer follow-up are unknown. Well-designed comparative trials with longer follow-up are needed to determine the effect of RFA on health outcomes compared with other treatment options such as myomectomy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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: *58580, 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.

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Chudnoff S, Guido R, Roy K, Levine D, Mihalov L, Garza-Leal JG. Ultrasound-Guided Transcervical Ablation of Uterine Leiomyomas. *Obstet Gynecol*. 2019;133(1):13-22. doi:10.1097/AOG.0000000000003032

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Lukes A and Green MA. Three-year results of the SONATA pivotal trial of transcervical fibroid ablation for symptomatic uterine myomata. J Gynecol Surg 2020;36:228.

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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

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Specialty Matched Consultant Advisory Panel 9/2022

Medical Director review 9/2022

Specialty Matched Consultant Advisory Panel 9/2023

Medical Director review 9/2023

Specialty Matched Consultant Advisory Panel 3/2024

Medical Director review 3/2024

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)
07/12/22	Added coverage for Acessa and Sonata. Policy Guidelines updates. References updated. Medical Director review 6/2022 (tt)
10/18/22	References updated. Specialty Matched Consultant Advisory Panel review 9/2022. Medical Director review 9/2022. No change to policy statement. (tt)
9/29/23	Policy guidelines updated. References updated. Specialty Matched Consultant Advisory Panel review 9/2023. Medical Director review 9/2023. No change to policy statement. (tt)
12/29/23	Updated Billing/Coding section to remove CPT code 0404T and added 58580, effective 1/1/2024. (tt)
4/1/24	References added. Specialty Matched Consultant Advisory Panel review 3/2024. Medical Director review 3/2024. No change to policy statement. (tt)