BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Laparoscopic, Percutaneous, and Transcervical Techniques for the Myolysis of Uterine Fibroids

Policy #: 208
Latest Review Date: February 2024
Category: Surgery

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage, the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD, are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual, Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after 4/15/2022:

Blue Advantage will treat **laparoscopic or transcervical radiofrequency ablation (RFA)** as a treatment of symptomatic uterine fibroids as a **covered benefit** in individuals 18 years and older when ALL of the following conditions are met:

- Evidence of uterine fibroids via ultrasound that are less than 10 cm in diameter for laparoscopic RFA with Acessa or 7 cm for transcervical RFA with Sonata; AND
- Individual desires a uterine-sparing treatment approach or is ineligible for hysterectomy or other uterine-sparing alternatives to RFA (e.g., laparoscopic myomectomy, uterine artery embolization [UAE]); AND
- Individual has experienced at least one of the following symptoms that are a direct result of the fibroid(s):
    - Menorrhagia or other abnormal uterine bleeding that interferes with daily activities or causes anemia*
    - Pelvic pain or pressure
    - Urinary symptoms (e.g., urinary frequency, urgency) related to bulk compression of the bladder
    - Gastrointestinal symptoms related to bulk compression of the bowel (e.g., constipation, bloating)
    - Dyspareunia (painful or difficult sexual relations).

*In individuals >45 years of age with menorrhagia or other abnormal bleeding, endometrial biopsy is recommended prior to treatment to rule out endometrial malignancy and/or additional assessment to rule out a risk for uterine leiomyosarcoma.

Blue Advantage will treat **reintervention with RFA** as a **covered benefit** for patients meeting policy criteria above with documentation of new or recurrent fibroid development following a partial response with the initial procedure.

Blue Advantage will treat **other laparoscopic, transcervical or percutaneous techniques for myolysis of uterine fibroids**, including use of laser or bipolar needles, cryomyolysis, and magnetic resonance imaging-guided laser ablation, as a **non-covered benefit** and as **investigational**.

Effective for dates of service prior to 4/15/2022:

Blue Advantage will treat **laparoscopic, percutaneous, and transcervical techniques of myolysis** as a **non-covered benefit** and as **investigational** for the treatment of uterine fibroids.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment, or procedure is one made between the physician and their patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most

appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Various minimally invasive treatments for uterine fibroids have been proposed as alternatives to surgery. Among these approaches are laparoscopic, percutaneous, and transcervical techniques to induce myolysis, which include radiofrequency ablation (RFA), laser and bipolar needles, cryomyolysis and magnetic resonance imaging (MRI)-guided laser ablation.

Uterine Fibroids

Uterine fibroids, also known as leiomyomas, are among the most common conditions affecting women in the reproductive years; symptoms include menorrhagia, pelvic pressure, or pain. It is estimated that uterine fibroids occur in up to 70% of women by menopause, with approximately 25% of these being clinically significant and requiring intervention.

Treatment

Surgery, including hysterectomy and various myomectomy procedures, is considered the criterion standard for symptom resolution. However, there is the potential for surgical complications, and in the case of a hysterectomy, the uterus is not preserved. In addition, multiple myomectomies may be associated with longer operating time, postoperative febrile morbidity and development of pelvic adhesions. 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) (see medical policy #022 – Occlusion of Uterine Arteries using Transcatheter Embolization or Laparoscopic Occlusion to Treat Uterine Fibroids) and magnetic resonance imaging-guided focused ultrasound therapy (see medical policy #178 – Magnetic Resonance Guided Focused Ultrasound).

Various techniques to induce myolysis have also been studied, including Nd: YAG lasers, bipolar electrodes, cryomyolysis and radiofrequency ablation. With these techniques, 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 or transcervically to determine fibroids' size and location, guide the probe, and 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.

KEY POINTS:

The most recent literature review was updated through December 20. 2023.

Summary of Evidence
For individuals who have symptomatic uterine fibroids who receive RFA, the evidence includes prospective cohorts, randomized controlled trials (RCT) and systematic reviews. The relevant outcomes are symptoms, QOL, and treatment-related morbidity. The meta-analysis found low rates of reintervention with RFA and QOL 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 non-inferior, and one RCT found that RFA was superior to laparoscopic myomectomy on the trial's 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 a faster recovery than myomectomy, and provides a reduction in symptoms and improvement in QOL in the short term. Additionally, clinical input was sought in 2021. The consensus was supportive of the use of laparoscopic or transcervical RFA for individuals with symptomatic uterine fibroids. These technologies provide a clinically meaningful improvement in the net health outcome and are consistent with generally accepted medical practice.

For individuals who have symptomatic uterine fibroids who receive laser or bipolar needles, the evidence includes case series. The relevant outcomes are symptoms, QOL, 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 evaluate the safety and efficacy of this technology adequately. 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 cryomyolysis, the evidence includes case series. The relevant outcomes are symptoms, QOL, and treatment-related morbidity.

Among the few case series, sample sizes were small (≤20 patients). RCTs comparing cryomyolysis with alternative treatments for uterine fibroids are needed to evaluate the safety and efficacy of this technology adequately. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

For individuals who have symptomatic uterine fibroids who receive MRI-guided laser ablation, the evidence includes a study with historical controls. The relevant outcomes are symptoms, QOL, and treatment-related morbidity. A single study with historical controls is not sufficiently robust to evaluate 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 that the technology results in an improvement in the net health outcomes.

Practice Guidelines and Position Statements

American College of Obstetricians and Gynecologists

In 2021, the American College of Obstetricians and Gynecologists updated its practice bulletin on the management of symptomatic leiomyomas. Recommendations based on a review of evidence included the following:

- Radiofrequency ablation can be considered as a minimally invasive treatment option in patients who desire to retain their uterus, provided they are counseled about the limited data on reproductive outcomes. Laparoscopic, transvaginal, or transcervical approaches using ultrasound guidance are considered similarly effective.
- Focused ultrasound is associated with a reduction in leiomyoma and uterine size but is associated with less improvement in symptoms and quality of life and a higher risk of reintervention compared with uterine artery embolization.
- Myomectomy was recommended as an option in patients who desire uterine preservation or future pregnancy and are counseled about the risk of recurrence. The laparoscopic approach is associated with shorter hospitalization, less postoperative pain, faster return to work, and earlier return to normal activities.
- Hysterectomy is recommended as a definitive surgical manage option in patients who do not desire future childbearing or do not wish to retain their uterus.

National Institute for Health and Care Excellence

In 2021, the National Institute for Health and Care Excellence (NICE) published an interventional procedures guidance on the use of transcervical ultrasound-guided radiofrequency ablation (RFA) for symptomatic uterine fibroids. The NICE guidance noted that while evidence on the safety of transcervical RFA raises no major safety concerns, evidence on the efficacy of the procedure is limited in quality. Therefore, NICE recommends that the procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

U.S. Preventive Services Task Force

Not applicable

KEY WORDS:

Uterine fibroids, leiomyomata, hysterectomy, myomectomy, myolysis, Nd: YAG laser, bipolar electrodes, cryomyolysis, radiofrequency ablation, MRI guidance, laparoscopic procedure, percutaneous procedure, ExAblate®, Acessa, Halt, cryoablation, interstitial laser photocoagulation of uterine fibroids, laser myolysis, RFA, transcervical, sonata system

APPROVED BY GOVERNING BODIES:

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 (K121858). 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 (K132744). FDA product code: GEI. 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. (K181124). Hologic acquired Accessa Health in 2020.

In 2018, the Sonata® Sonography-Guided Transcervical Ablation System (Gynesonics, Inc, Redwood City, CA) was cleared for marketing by the FDA through the 510(k) process for diagnostic intrauterine imaging and transcervical 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.

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

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

58674	Laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency

The following unlisted codes might be used for other non-RFA laparoscopic, transcervical, or percutaneous techniques for myolysis of uterine fibroids.

58578	Unlisted laparoscopy procedure, uterus
58999	Unlisted procedure, female genital system (non-obstetrical)

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 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	Ultrasound guidance, intraoperative

For transcervical fibroid ablation:

58580	Transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency (Effective 1/1/24)

PREVIOUS CODING:

For transcervical fibroid ablation:

0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency **(Deleted 12/31/23)**

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POLICY HISTORY:

Adopted for Blue Advantage, March 2005
Available for comment May 1-June 14, 2005
Medical Policy Group, October 2006
Medical Policy Group, October 2008
Medical Policy Group, October 2010
Medical Policy Group, September 2012: Active Policy but no longer scheduled for regular literature reviews and updates.
Medical Policy Group, September 2013
Medical Policy Group, December 2013
Medical Policy Group, April 2014
Medical Policy Group, July 2014
Medical Policy Group, July 2015
Medical Policy Group, August 2016
Medical Policy Group, December 2016
Medical Policy Group, August 2017
Medical Policy Group, August 2018 **(4)**: Updates to Key Points, Approved by Governing Bodies, and References. No change to policy statement.
Medical Policy Group, August 2019
Medical Policy Group, March 2020: Added CPT code 0404T.
Medical Policy Group, September 2020
Medical Policy Group, February 2022
Medical Policy Group, April 2022: Clarified Current coding section by adding verbiage above unlisted codes to include "other non RFA laparoscopic, transcervical, or percutaneous techniques for myolysis of uterine fibroids."
Medical Policy Group, February 2023

Medical Policy Group, November 2023: 2024 Coding Update. Added new code 58580 to Current coding and created Previous coding section. Removed deleted code 0404T from Current coding and added to Previous coding. New code effective 1/1/2024 and deleted code effective 12/31/2023.
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, February 2024
UM Committee, February 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.
