BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

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

Policy #: 208
Category: Surgery

Latest Review Date: September 2020
Policy Grade: B

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 July 1, 2005:

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

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 his/her 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 includes radiofrequency volumetric thermal ablation (RFVTA), 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.

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 hysterectomy, the uterus is not preserved. In addition, multiple myomectomy 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. 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 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 and transcervical approaches using MRI guidance have also been reported.

KEY POINTS:

The most recent literature review was updated through June 26, 2020.

Summary of Evidence

For individuals who have symptomatic uterine fibroids who receive RFA, the evidence includes prospective cohorts, a randomized controlled trial (RCT) and systematic review. 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 study and no studies reported reintervention rates at 60 months. The RCT with a follow-up longer than three months 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 QOL. None of the secondary outcomes demonstrated significant between-group differences in a subgroup analysis of 43 patients. The procedure has a faster recovery than myomectomy, and provides a reduction in symptoms and improvement in QOL 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 the effects of the technology on health outcomes.

For individuals who have uterine fibroids who receive transcervical fibroid ablation, the evidence includes a single cohort study, prospective and retrospective studies. The relevant outcomes are safety, efficacy, QOL, symptoms, and surgical reintervention. A retrospective 5 year study was completed, but it only included 23 women. The SONATA pivotal IDE trial was a prospective, controlled, multi-center interventional trial that evaluated the safety and efficacy of transcervical fibroid ablation up to 3 years. There are no randomized controlled trials noted comparing this with other treatment options such as myomectomy. Well-designed head to head trials with long term results are needed. Currently, the evidence is not sufficient to determine health outcomes for this procedure.

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 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. 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 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. The relevant outcomes are symptoms, QOL, and treatment-related morbidity. A single study with historical controls (N=66) 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 the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
American College of Obstetricians and Gynecologists
In 2019, the American College of Obstetricians and Gynecologists reaffirmed a 2008 Practice Bulletin titled "Alternatives to Hysterectomy in the Management of Leiomyomas". 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
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 November 2012, the Acessa™ System (Acessa Health, Austin, TX, formerly Halt Medical) 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 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). In 2014, the ultrasound guidance system received marketing clearance from the FDA (K132744). 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).

In August 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 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 a laparoscopic procedure.

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:

0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency

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POLICY HISTORY:

Adopted for Blue Advantage, March 2005
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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