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FEP Medical Policy Manual

FEP 4.01.19 Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Effective Policy Date: July 1, 2023

Original Policy Date: September 2013

Related Policies:

7.01.109 - Magnetic Resonance Imaging-Guided Focused Ultrasound

Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis

Description

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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 ablation (RFA), laser and bipolar needles, cryomyolysis, and magnetic resonance imaging-guided laser ablation.

OBJECTIVE

The objective of this evidence review is to determine whether laparoscopic, percutaneous, and/or transcervical techniques to induce myolysis improve the net health outcome in individuals with uterine fibroids.

POLICY STATEMENT

Laparoscopic or transcervical radiofrequency ablation (RFA) as a treatment of symptomatic uterine fibroids is considered **medically necessary** 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]) (see Policy Guidelines); AND
- Individual has experienced at least 1 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 (see Policy Guidelines);
    - 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).

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, are considered **investigational**.

POLICY GUIDELINES

Eligibility Considerations

Abnormal uterine bleeding refers to uterine bleeding of abnormal frequency, duration, and volume that interferes with an individual's quality of life. Individuals with abnormal uterine bleeding with an inadequate response to appropriately selected medical therapy may be considered for alternate uterine-sparing interventions. 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.

Clinical trial experience with radiofrequency ablation (RFA) has been limited to patients with overall uterine size ≤16 gestational weeks size based on pelvic examination. In individuals where fibroids cannot be distinguished from adenomyosis on ultrasound, advanced imaging (e.g., magnetic resonance imaging [MRI]) may be required. For individuals with pelvic pain, alternative causes such as endometritis and active pelvic inflammatory disease should be excluded prior to treatment with RFA.

Treatment Approach Considerations for Radiofrequency Ablation

Uterine fibroids are categorized according to the International Federation of Gynaecology and Obstetrics (FIGO) leiomyoma subclassification system (see Table PG1). Choice of laparoscopic versus transcervical RFA treatment is dependent on fibroid number, size, type and location, and individual preferences. For example, predominantly lower uterine segment or cervical leiomyomata, or those with a predominant submucosal location or intramural FIGO type 2 or 3 fibroids, may suggest a transcervical approach, whereas fibroids with largely fundal or extramural components may suggest a laparoscopic approach. Individuals aiming to avoid future deliveries via obligate cesarean section may prefer a transcervical approach. Select individuals with numerous fibroids may benefit from combined laparoscopic RFA and laparoscopic myomectomy. Individuals with intramural fibroids, intra-abdominal adhesions, or medical contraindications may not be candidates for alternative uterine-sparing interventions.

Table PG1. International Federation of Gynaecology and Obstetrics (FIGO) Leiomyoma Subclassification System

Group	Type	Description
Submucosal	0	Pedunculated intracavitary
	1	<50% intramural (≥50% submucosal)

	2	≥50% intramural (<50% submucosal)
Other	3	100% intramural, contacting endometrium
	4	100% intramural, no endometrial or subserosal contact
	5	Subserosal, ≥50% intramural
	6	Subserosal, <50% intramural
	7	Pedunculated subserosal
	8	Non-myometrial location (eg, cervical, broad ligament, parasitic)
Hybrid	X-X	Both submucosal and subserosal components. Submucosal component designated by first number and subserosal component designated by second number.

Table adapted from Gomez et al (2021). MRI-based pictorial review of the FIGO classification system for uterine fibroids. Abdom Radiol. 46(5): 2146-2155. PMID: 33385249.

Reinterventions

Reintervention with RFA may be considered for individuals meeting policy criteria with documentation of new or recurrent fibroid development following a partial response with the initial procedure. However, data on reinterventions for new or recurrent fibroids is limited and documentation procedures for repeat anatomic mapping of fibroids are not standardized.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Some of the lysis procedures are specialized and not widely disseminated; therefore, requests for out-of-network referral may occur.

FDA 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 (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. FDA product code: HFG.

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.

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 (eg, Nd:YAG lasers, bipolar electrodes) have long-standing FDA approval, and there are no products specifically approved for the treatment of uterine fibroids.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-labeling-laparoscopic-power-morcellators).

RATIONALE

Summary of Evidence

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 symptomatic 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 then may not reflect current practice. RCTs comparing laser or bipolar needles 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 outcome.

For individuals who have symptomatic 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 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 outcome.

For individuals who have symptomatic uterine fibroids who receive magnetic resonance imaging (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 not sufficiently robust to evaluate this technology. RCTs comparing MRI-guided laser ablation with alternative treatments for uterine fibroids are needed to evaluate safety and efficacy adequately. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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.[1,] 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 management 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, NICE published an interventional procedures guidance on the use of transcervical ultrasound-guided RFA for symptomatic uterine fibroids.[39,] 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 Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2013	New policy	
September 2014	Replace policy	Policy updated with literature review. References 2, 4, and 15 added.Policy statement unchanged.
September 2015	Replace policy	Policy updated with literature review; references 5 and 15 added. Policy statement unchanged.
September 2016	Replace policy	Policy updated with literature review; references 3-4 added. Policy statement unchanged.
December 2017	Replace policy	Policy updated with literature review through 2017; references 7 and 18added. Policy statement unchanged.
December 2018	Replace policy	Policy updated with literature review through June 4, 2018; reference 2added. Policy statement unchanged.
December 2019	Replace policy	Policy updated with literature review through June 16, 2019; references added. Policy statement unchanged.
December 2020	Replace policy	Policy updated with literature review through June 26, 2020; references added. Policy statement unchanged.
March 2022	Replace policy	Policy updated with clinical input and literature review through January 3, 2022; references added. Title changed to "Laparoscopic, percutaneous, and transcervical techniques for uterine fibroid myolysis." Policy statements revised. Use of laparoscopic or transcervical radiofrequency ablation for the treatment of symptomatic uterine fibroids may be considered medically necessary in patients meeting criteria. Use of laser or bipolar needles, cryomyolysis, or MRI-guided laser ablation maintained as investigational. Policy previously tabled in 2021 to obtain clinical input.
June 2022	Administrative Review	No change in policy statements or references.
June 2023	Replace policy	Policy updated with literature review through December 19, 2022; references added. Minor editorial refinements to policy statements; intent unchanged.