MEDICAL POLICY

POLICY TITLE	**LAPAROSCOPIC, PERCUTANEOUS, AND TRANSCERVICAL TECHNIQUES FOR UTERINE FIBROID MYOLYSIS**
POLICY NUMBER	**MP 7.027**

CLINICAL BENEFIT	☒ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**5/1/2025**

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I. POLICY

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;
    - 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**. There is insufficient evidence to support a general conclusion concerning the health outcomes benefits associated with procedure.

Policy Guidelines

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 individual with overall uterine size ≤16 gestational week's 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.

Cross-References:

MP 5.053 Magnetic Resonance–Guided Focused Ultrasound
MP 7.013 Endometrial Ablation

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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Uterine Fibroids

Uterine fibroids, also known as leiomyomas, are among the most common conditions affecting women in their 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. The prevalence rate of uterine fibroids is 2-3 times higher among Black women compared with White women, and there are higher rates of hysterectomy and myomectomy compared with non-surgical therapy, potentially demonstrating a disparity in access to uterine-sparing interventions.

Treatment

Surgery, including hysterectomy and various myomectomy procedures, is considered the gold 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 long-standing research interest in developing minimally invasive alternatives for treating uterine fibroids, including procedures that retain the uterus and permit future childbearing. Treatment options include uterine artery embolization and transcutaneous magnetic resonance imaging-guided focused ultrasound therapy. 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 multiple insertions of probes into the fibroid, 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 repetitive insertions of needle electrodes, but instead integrate the energy delivery and real-time imaging within a single device. This technology has also shown clinically significant reduction in symptoms, has little to no adverse events, and provides a safe option for women who desire fertility.

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 approaches using magnetic resonance imaging 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 (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). FDA product code: HFG.

In 2018, the Sonata® Sonography-Guided Transcervical Fibroid Ablation System (Gynsonics) 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. 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 (e.g., Nd: YAG lasers, bipolar electrodes) have long-standing FDA approval, and there are no products specifically approved for the treatment of uterine fibroids.

IV. RATIONALE

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Summary of Evidence

For individuals who have symptomatic uterine fibroids who receive RFA, the evidence includes prospective cohorts, 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 to laparoscopic myomectomy on the primary outcome: length of hospitalization. A number of secondary outcomes were reported at 12 and 24 months in 1 RCT, including symptoms and quality of life. None of the secondary outcomes demonstrated significant between-group differences in a subgroup analysis of 43 patients. 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-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 magnetic resonance imaging-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.

Practice Guidelines and Position Statements

The American College of Obstetricians and Gynecologists (ACOG)
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 management option in patients who do not desire future childbearing or do not wish to retain their uterus.

National Institute for Health 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 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, the NICE recommends that the procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

V. DEFINITIONS

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N/A

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations are based on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits. These medical policies do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when Medically Necessary when used for Laparoscopic ultrasound-guided radiofrequency ablation

Procedure Codes							
58578	58580	58674	58999				

Investigational therefore not covered when used for Cryomyolysis, Magnetic resonance imaging-guided laser ablation:

Procedure Codes							
58578	58999						

IX. REFERENCES

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X. POLICY HISTORY

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MP 7.027	**09/03/2020 Consensus Review.** No change to policy statement. Rationale updated
	09/09/2021 Minor Review. Laparoscopic US guided RFA is now MN. Coding, background, rationale, and references updated.
	04/25/2022 Minor Review. Transcervical RFA changed from INV to MN with criteria. Criteria updated for Laparoscopic RFA. Policy Guidelines added. Coding, background, rationale, and references updated.
	03/29/2023 Consensus Review. No change to policy statement. Updated background and references.
	02/16/2024 Consensus Review. No change to policy statement. Updated references.
	02/14/2025 Consensus Review. No changes to policy stance.

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