



Louisiana

Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids

Policy # 00445

Original Effective Date: 09/17/2014

Current Effective Date: 11/09/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Occlusion of Uterine Arteries Using Transcatheter Embolization or Laparoscopic Occlusion to Treat Uterine Fibroids is addressed separately in medical policy 00130.

Note: Magnetic Resonance-Guided Focused Ultrasound is addressed separately in medical policy 00180.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers laparoscopic and percutaneous techniques of myolysis as a treatment of uterine fibroids are considered to be **investigational**.*

Policy Guidelines

In November 2014, the U.S. Food and Drug Administration published a safety communication on laparoscopic power morcellators used for myomectomy and hysterectomy in most women. (Morcellators are not otherwise addressed herein). The Administration recommended that manufacturers of these devices include in their product labels a boxed safety warning and wording on contraindications

(see

<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM424123.pdf>).

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Background/Overview

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.

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 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 (see medical policy 00130) and the transcatheter magnetic resonance imaging-guided focused ultrasound therapy (see medical policy 00180). 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. 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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

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System. In 2014, the ultrasound guidance system received marketing clearance from the FDA (K132744). FDA product code: GEI. In 2018, the third-generation Acesa^{TM‡} 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 (eg, Nd:YAG lasers, bipolar electrodes) have long-standing FDA approval, and there are no products specifically approved for the treatment of uterine fibroids.

Rationale/Source

Description

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

Summary of Evidence

For individuals who have symptomatic uterine fibroids who receive RFA, the evidence includes prospective cohorts, an RCT and systematic review. 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 study and no studies reported reintervention rates at 60 months. The single RCT with a follow-up longer than 3 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 quality of life. None of the secondary outcomes demonstrated significant between-

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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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

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Supplemental Information

Practice Guidelines and Position Statements

American College of Obstetricians and Gynecologists

In 2019, the American College of Obstetricians and Gynecologists reaffirmed its 2008 position on alternatives to hysterectomy in the management of leiomyomas. Recommendations based on good and consistent scientific evidence were that abdominal myomectomy is a safe and effective treatment for women with symptomatic leiomyomas and that uterine artery embolization is a safe and effective option for appropriately selected women who want to retain their uteri. The bulletin contained no recommendations on myolysis using laparoscopic or percutaneous techniques.

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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this evidence review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02260752	Patient-Centered Results for Uterine Fibroids (COMPARE-UF)	3,094	Sep 2020 published
NCT01563783 ^a	The Trust (Treatment Results of Uterine Sparing Technologies) Study	260	Jun 2022

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NCT03219385	Directed Ablation of Uterine Fibroids Using a Noninvasive Approach (DIANA)	180	Sep 2022
NCT03118037	Transcervical Radiofrequency Ablation of Uterine Fibroids Global Registry (SAGE)	100	Dec 2023
NCT02163525 ^a	Post Market TRUST - U.S.A. Study	114	Jun 2024
NCT02100904	Uterine Leiomyoma Treatment With Radiofrequency Ablation (ULTRA) Registry (ULTRA Registry)	400	Jan 2025
<i>Unpublished</i>			
NCT01750008 ^a	The LUSTOR (Laparoscopic Uterine Sparing Techniques Outcomes and Reinterventions) Trial	51	Jun 2018

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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|------------|---|
| 09/04/2014 | Medical Policy Committee review |
| 09/17/2014 | Medical Policy Implementation Committee approval. New policy. |
| 08/03/2015 | Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed. |
| 09/03/2015 | Medical Policy Committee review |
| 09/23/2015 | Medical Policy Implementation Committee approval. No change to coverage. |
| 01/01/2016 | Coding update |
| 09/08/2016 | Medical Policy Committee review |
| 09/21/2016 | Medical Policy Implementation Committee approval. No change to coverage. |
| 01/01/2017 | Coding update: Removing ICD-9 Diagnosis Codes and CPT coding update |
| 10/05/2017 | Medical Policy Committee review |
| 10/18/2017 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 10/04/2018 | Medical Policy Committee review |

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10/17/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

10/03/2019 Medical Policy Committee review

10/09/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

10/01/2020 Medical Policy Committee review

10/07/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 10/2021

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0404T, 58674, 76940, 77022
HCPCS	No codes
ICD-10 Diagnosis	D25.0-D25.9

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

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