MASSACHUSETTS

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Medical Policy

Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids

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Policy Number: 244

BCBSA Reference Number: 4.01.19
NCD/LCD: N/A

Related Policies

- MRI-Guided Focused Ultrasound for the Treatment of Uterine Fibroids and Other Tumors, #243
- Occlusion of Uterine Arteries Using Transcatheter Embolization, #242

Policy[i]

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Laparoscopic or Hysteroscopic ultrasound-guided radiofrequency ablation (e.g., Acessa™ or Sonata™) for the treatment of uterine fibroids in women 18 and older may be considered **MEDICALLY NECESSARY** when **ALL** of the following conditions are met:

- Evidence of uterine fibroids via ultrasound that are less than 10cm in diameter for Acessa™ or 7cm for Sonata™, **and**
- Member desires a uterine sparing treatment approach or is contraindicated for hysterectomy, **and**
- Member has experienced any one of the following symptoms that are a direct result of the fibroid(s):
  - Menorrhagia interferes with daily activities or causes anemia; **or**
  - Pelvic pain or pressure, **or**
  - Lower back pain; **or**
  - Urinary symptoms (e.g., urinary frequency, urgency) related to compression of the bladder; **or**
  - Gastrointestinal symptoms related to compression of the bowel (e.g., constipation, bloating); **or**
  - Dyspareunia (painful or difficult sexual relations).

Laparaoscopic ultrasound-guided radiofrequency ablation is considered **INVESTIGATIONAL** in all other situations, but not limited to:

- When there has been a diagnosis of cancer (or pre-cancerous lesions) anywhere in the pelvis, **or**
- In patients who are diagnosed with or at risk for leiomyosarcoma, **or**
- In patients with acute pelvic inflammatory disease, **or**
- In patients with abnormal pap smear test results.

Laparoscopic and percutaneous techniques of myolysis in any other circumstance, including but not limited to, MRI Laser ablation, cryomyolysis, or the use of laser ablation using bipolar needles, is considered **INVESTIGATIONAL**.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not** required.
Commercial PPO and Indemnity	Prior authorization is **not** required.
Medicare HMO Blue℠	Prior authorization is **not** required.
Medicare PPO Blue℠	Prior authorization is **not** required.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency

Description

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 MP #242) and the transcutaneous magnetic

resonance imaging-guided focused ultrasound therapy (see MP #243). 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[1,] Newer systems using radiofrequency energy do not require repetitive insertions of needle electrodes. Ultrasonography is used laparoscopically 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.

Summary

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 volumetric thermal ablation (RFVTA), laser and bipolar needles, cryomyolysis, and magnetic resonance imaging-guided laser ablation.

For individuals who have symptomatic uterine fibroids who receive RFVTA, the evidence includes 2 randomized controlled trials and a series of longitudinal meta-analyses comparing primary outcomes of RFVTA to current standards of care, i.e., complete hysterectomy, laparoscopic myectomy, myomectomy and medication management. The relevant outcomes are symptoms, quality of life and treatment-related morbidity. The randomized controlled trials found patients experienced faster recovery periods, reduced bleeding, and significant reduction of pain when compared with laparoscopic myomectomy or hysterectomy. Individuals from both groups demonstrated similar reduction of fibroid volume, decreased uterine volume and decreased menstrual bleeding. All of the studies found that RFVTA was effective in mapping and ablating fibroids and was associated with less blood loss during the procedure. Data on reintervention rates at 36 months from the HALT trial, demonstrated that there was clinically significant improvement in quality of life scores including engagement in activities, energy/mood, bladder and bowel control and sexual function. Results from the HALT trial indicated a reintervention rate of 11% by 36 months. Other trials are available demonstrating the safety and effectiveness of RFVTA in women who plan to conceive and go on to achieve live birth. The evidence is sufficient to determine that the technology results in a meaningful improvement in health outcomes.

For individuals who have symptomatic uterine fibroids who receive hysteroscopic ultrasound guided radiofrequency ablation (transcervical fibroid ablation TFA), the evidence includes multiple clinical trials and comparative, systematic reviews. The relevant outcomes are symptom improvement, quality of life, and reintervention rates. Patients treated with TFA did not require the use of anesthesia prior to the procedure and were able to return home on the same day. More than half of the respondents were able to resume normal activities after 1 day, post procedure. Zero participants from the pivotal clinical trial experienced adverse events and 96% of patients demonstrated continued symptom improvement after 12 months. Many controlled trials and case reviews are available demonstrating safety and efficacy data for 1, 3, and 5-year periods in patients who have undergone TFA. The evidence is sufficient to determine that the technology results in a meaningful improvement in health outcomes.

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 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. 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 symptomatic uterine fibroids who receive magnetic resonance imaging-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 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.

Policy History

Date	Action
10/2020	New medically necessary indications added for laparoscopic and hysteroscopic radiofrequency ablation for the treatment of uterine fibroids. Clarified coding information, 10/1/2020.
10/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
10/2018	BCBSA National medical policy review. No changes to policy statements. New references added. Background and summary clarified.
9/2017	New references added from BCBSA National medical policy.
1/2017	Clarified coding information for the 2017 code changes.
10/2016	New references added from BCBSA National medical policy.
8/2015	New references added from BCBSA National medical policy.
9/2014	New references added from BCBSA National medical policy.
6/2014	Coding information clarified.
10/2013	New references from BCBSA National medical policy.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/2011	Reviewed - Medical Policy Group - Urology, Obstetrics and Gynecology. No changes to policy statements.
10/2010	Reviewed - Medical Policy Group - Obstetrics and Gynecology. No changes to policy statements.
7/2010	Medical Policy 244 effective 7/10 describing on-going non-coverage

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

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[i] Based on expert opinion.