



FEP Medical Policy Manual

FEP 4.01.19 Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids

Effective Policy Date: January 1, 2020

Original Policy Date: September 2013

Related Policies:

4.01.11 - Occlusion of Uterine Arteries Using Transcatheter Embolization
7.01.109 - Magnetic Resonance Imaging–Guided Focused Ultrasound

Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids

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

OBJECTIVE

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

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

POLICY STATEMENT

Laparoscopic and percutaneous techniques of myolysis as a treatment of uterine fibroids are considered **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>).

BENEFIT APPLICATION

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

FDA REGULATORY STATUS

In 2012, the Acesa™ System (Acesa 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 Acesa™ 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.

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

Summary of Evidence

For individuals who have symptomatic uterine fibroids who receive radiofrequency volumetric thermal ablation (RFVTA), the evidence includes a randomized controlled trial (RCT) and systematic review. The relevant outcomes are symptoms, quality of life (QOL), and treatment-related morbidity. The meta-analysis found low rates of reintervention with RFVTA 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 single RCT with a follow-up longer than three months found that RFVTA 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. Additional well-designed RCTs with longer follow-up are needed to determine the effect of RFVTA on health outcomes compared with other treatment options. 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. 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.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Obstetricians and Gynecologists

The American College of Obstetricians and Gynecologists (2019) reaffirmed its 2008 position on alternatives to hysterectomy in the management of leiomyomas.^{18,19} 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.

REFERENCES

1. Jones S, O'Donovan P, Toub D. Radiofrequency ablation for treatment of symptomatic uterine fibroids. *Obstet Gynecol Int.* Oct 2012;2012:194839. PMID 21961009.
2. Sandberg EM, Tummers F, Cohen SL, et al. Reintervention risk and quality of life outcomes after uterine-sparing interventions for fibroids: a systematic review and meta-analysis. *Fertil Steril.* Apr 2018;109(4):698-707 e691. PMID 29653718.
3. Havryliuk, YY, Setton, RR, Carlow, JJ, Shaktman, BB. Symptomatic Fibroid Management: Systematic Review of the Literature. *JSLs*, 2017 Sep 28;21(3). PMID 28951653.
4. Lin, LL, Ma, HH, Wang, JJ. Quality of Life, Adverse Events, and Reintervention Outcomes after Laparoscopic Radiofrequency Ablation for Symptomatic Uterine Fibroids: A Meta-Analysis. *J Minim Invasive Gynecol*, 2018 Sep 27;26(3). PMID 30253997.
5. Brucker SY, Hahn M, Kraemer D, et al. Laparoscopic radiofrequency volumetric thermal ablation of fibroids versus laparoscopic myomectomy. *Int J Gynaecol Obstet.* Jun 2014;125(3):261-265. PMID 24698202.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

6. Kramer B, Hahn M, Taran FA, et al. Interim analysis of a randomized controlled trial comparing laparoscopic radiofrequency volumetric thermal ablation of uterine fibroids with laparoscopic myomectomy. *Int J Gynaecol Obstet.* May 2016;133(2):206-211. PMID 26892690.
7. Hahn M, Brucker S, Kraemer D, et al. Radiofrequency volumetric thermal ablation of fibroids and laparoscopic myomectomy: long-term follow-up from a randomized trial. *Geburtshilfe Frauenheilkd.* May 2015;75(5):442-449. PMID 26097247.
8. Keltz J, Levie M, Chudnoff S. Pregnancy outcomes after direct uterine myoma thermal ablation: review of the literature. *J Minim Invasive Gynecol.* May - Jun 2017;24(4):538-545. PMID 28109894.
9. Goldfarb HA. Bipolar laparoscopic needles for myoma coagulation. *J Am Assoc Gynecol Laparosc.* Feb 1995;2(2):175-179. PMID 9050553.
10. Goldfarb HA. Nd:YAG laser laparoscopic coagulation of symptomatic myomas. *J Reprod Med.* Jul 1992;37(7):636-638. PMID 1387912.
11. Nisolle M, Smets M, Malvaux V, et al. Laparoscopic myolysis with the Nd:YAG laser. *J Gynecol Surg.* Summer 1993;9(2):95-99. PMID 10171973.
12. Donnez J, Squifflet J, Polet R, et al. Laparoscopic myolysis. *Hum Reprod Update.* Nov-Dec 2000;6(6):609-613. PMID 11129695.
13. Phillips DR, Nathanson HG, Milim SJ, et al. Laparoscopic leiomyoma coagulation. *J Am Assoc Gynecol Laparosc.* Aug 1996;3(4 Suppl):S39. PMID 9074213.
14. Zreik TG, Rutherford TJ, Palter SF, et al. Cryomyolysis, a new procedure for the conservative treatment of uterine fibroids. *J Am Assoc Gynecol Laparosc.* Feb 1998;5(1):33-38. PMID 9454874.
15. Zupi E, Piredda A, Marconi D, et al. Directed laparoscopic cryomyolysis: a possible alternative to myomectomy and/or hysterectomy for symptomatic leiomyomas. *Am J Obstet Gynecol.* Mar 2004;190(3):639-643. PMID 15041993.
16. Zupi E, Marconi D, Sbracia M, et al. Directed laparoscopic cryomyolysis for symptomatic leiomyomata: one-year follow up. *J Minim Invasive Gynecol.* Jul-Aug 2005;12(4):343-346. PMID 16036195.
17. Hindley JT, Law PA, Hickey M, et al. Clinical outcomes following percutaneous magnetic resonance image guided laser ablation of symptomatic uterine fibroids. *Hum Reprod.* Oct 2002;17(10):2737-2741. PMID 12351555.
18. American College of Obstetricians Gynecologists. ACOG practice bulletin. Alternatives to hysterectomy in the management of leiomyomas. *Obstet Gynecol.* Aug 2008;112(2 Pt 1):387-400. PMID 18669742.
19. American College of Obstetricians and Gynecologists (ACOG). Alternatives to hysterectomy in the management of leiomyomas. ACOG practice bulletin No. 96. reaffirmed 2019; <http://www.acog.org/-/media/List-of-Titles/PBListOfTitles.pdf>. Accessed July 2, 2019.

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.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

Date	Action	Description
December 2017	Replace policy	Policy updated with literature review through 2017; references 7 and 18 added. Policy statement unchanged.
December 2018	Replace policy	Policy updated with literature review through June 4, 2018; reference 2 added. Policy statement unchanged.
December 2019	Replace policy	Policy updated with literature review through June 16, 2019; references added. Policy statement unchanged.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.