MEDICAL POLICY

POLICY TITLE	LAPAROSCOPIC AND PERCUTANEOUS TECHNIQUES FOR THE MYOLYSIS OF UTERINE FIBROIDS
POLICY NUMBER	MP-7.027

Original Issue Date (Created):	**8/1/2014**
Most Recent Review Date (Revised):	**9/3/2020**
Effective Date:	**12/1/2020**

I. POLICY

Laparoscopic and percutaneous techniques of myolysis as a treatment of uterine fibroids are considered **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes benefits associated with this procedure.

Cross-references:

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

II. PRODUCT VARIATIONS

TOP

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

FEP PPO - Refer to FEP Medical Policy Manual MP-4.01.19, Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids. 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

TOP

Uterine Fibroids
Uterine fibroids 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 treatment for symptom resolution. However, there is the potential for surgical

complications and, in the case of hysterectomy, the uterus is not preserved. In addition, multiple myomectomy 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 the transcutaneous procedure 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. 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.

REGULATORY STATUS

In November 2012, the Acessa™ System (Acessa Health, Austin, TX, 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. The technology was previously approved in 2010, at which time it was called the Halt 2000GI™ Electrosurgical Radiofrequency Ablation System. The intended use of the Halt 2000GI™ system was for percutaneous laparoscopic coagulation and ablation of soft tissue. Unlike FDA clearance of the Acessa™ System, the intended use statement for the Halt 2000GI™ system does not specifically mention the treatment of uterine fibroids. FDA product code: GEI.

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 FDA. Other products addressed in this review (e.g., Nd:YAG lasers, bipolar electrodes) have long-standing FDA approval, and there are not products specifically approved for treatment of uterine fibroids.

IV. RATIONALE

TOP

Summary of Evidence

For individuals who have symptomatic uterine fibroids who receive RFVTA, the evidence includes an RCT and systematic review. The relevant outcomes are symptoms, 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.

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.

V. DEFINITIONS

TOP

N/A

VI. BENEFIT VARIATIONS

TOP

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 should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member’s health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and

providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

TOP

Capital BlueCross's medical policies are developed to assist in administering a member's benefits, 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 BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

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.

Investigational therefore not covered when used for Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids:

CPT Codes®							
58578	58674	58999					

IX. REFERENCES

TOP

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*
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. 2016; http://www.acog.org/-/media/List-of-Titles/PBListOfTitles.pdf. Accessed September 3, 2020.*

20. Blue Cross Blue Shield Association Medical Policy Reference Manual. 4.01.19, Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids. September 2019.

X. POLICY HISTORY

TOP

MP-7.027	**CAC 3/25/14. New policy. BCBSA adopted.** Laparoscopic and percutaneous techniques of myolysis as a treatment of uterine fibroids are considered investigational. Policy coded.
	CAC 3/24/15 Consensus review. No change to policy statements. References and rationale updated. Codes reviewed.
	CAC 3/29/16 Consensus review.No change to policy statements. References and rationale updated**.** Coding reviewed.
	11/15/16 Administrative update. Variation Reformatting
	1/1/17 Administrative update. End dated code 0336T removed and new code 58674 added; effective 1/1/17.
	CAC 3/28/17 Consensus review. No change to policy statements. References and rationale updated**.** Coding reviewed.
	12/29/17 Consensus review. No change to policy statements. Background, rationale and references updated.
	11/16/18 Consensus review. No change to policy statements. Background and references updated. Rationale condensed.
	9/9/19 Consensus review. No change to policy statements. References updated.
	9/3/20 Consensus review. No change to policy statement. Rationale updated

Top