



Clinical Policy Title: Radiofrequency ablation of uterine fibroids

Clinical Policy Number: 12.03.04

Effective Date: October 1, 2015
Initial Review Date: April 15, 2015
Most Recent Review Date: April 10, 2018
Next Review Date: April 2020

Policy contains:

- Radiofrequency ablation (RFA).
- Uterine fibroids.
- Leiomyoma.

Related policies:

- CP# 12.03.02** Uterine artery embolization
- CP# 12.03.03** Endometrial ablation
- CP# 13.01.02** Transvaginal and transabdominal ultrasound
- CP# 12.03.01** Leiomyosarcoma and laparoscopic power morcellation

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers the use of radiofrequency ablation for symptomatic uterine fibroids to be investigational and, therefore, not medically necessary.

Limitations:

This clinical policy applies only to the use of radiofrequency ablation for symptomatic uterine fibroids and does not apply to any other medically necessary and covered use of this technology.

Alternative covered services:

- Abdominal or laparoscopic myectomy.
- Hysterectomy.

- Medical therapies.
- Uterine artery embolization.

Background

Uterine fibroids (leiomyomata) are common in women of childbearing age (Office of Women's Health, 2015). In many women, leiomyomata shrink at menopause. Up to half of these benign masses can cause symptoms such as intense bleeding and debilitating pain in many sufferers, requiring treatment. Some cases can be addressed pharmacologically, while many require surgery. The most common surgical procedure for treatment of uterine fibroids in the United States is hysterectomy.

The invasive nature of hysterectomies, often with lengthy recovery periods and high costs, has created an incentive to develop uterine-preserving techniques that are less invasive and costly. They include myomectomy, which removes the fibroids but not the uterus, and uterine artery embolization (American College of Obstetricians and Gynecologists [ACOG], 2011). While less invasive, uterine artery embolization has been associated with a relatively high proportion of cases that require another intervention, including hysterectomy.

Radiofrequency ablation of symptomatic uterine fibroids is a minimally invasive ablation method that destroys tumors by local application of heat. The U.S. Food and Drug Administration (FDA) has approved the 2000GI™ Electrosurgical Radiofrequency Ablation System and the Acessa System™ both by Hault Medical Inc., Brentwood, California (FDA, 2010; FDA, 2012). In 2014, the FDA approved an investigational device exemption to carry out the Sonography Guided Transcervical Ablation of Uterine Fibroids (SONATA Trial) with the VizAblate® System (Gynesonics Inc., Redwood City, California) (BusinessWire, 2014).

Searches

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality's National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on March 8, 2018. Search terms were: ““Ablation Techniques” [MeSH], and “Leiomyoma” [MeSH], and free text terms “radiofrequency ablation,” “uterine fibroid,” and “leiomyoma.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**

- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

The evidence consists of several small, uncontrolled case series and one randomized controlled trial (RCT) comparing radiofrequency ablation to myomectomy. All but two studies were short-term in nature, most covering one year or less post-procedure. The RCT compared outcomes for 25 women undergoing radiofrequency ablation with 25 undergoing laparoscopic myomectomy (Brucker, 2014).

Limited evidence suggests radiofrequency ablation improves health-related quality of life (HRQoL) in the short-term and reduces symptom severity, the number of fibroids, peri-procedural blood loss, and surgical/hospitalization time. However, definitive patient selection criteria for radiofrequency ablation are lacking. Inadequate reporting of the patient and disease characteristics limited the ability to determine whether the populations studied reflected the larger populations from which they were drawn and to whom study results are intended to apply. In a broader context, each uterine-conserving intervention carries a specific safety and effectiveness profile; therefore, the best candidates for one option may not be the best candidates for another.

Neither the ACOG nor the Society of Obstetricians and Gynaecologists of Canada recommend radiofrequency ablation for treating uterine fibroids, citing a lack of long-term effectiveness data (ACOG, 2008; Vilos, 2015). Larger RCTs are needed to assess the relative effectiveness of available uterine-conserving options for uterine fibroids.

Policy updates:

We identified one new systematic review/health technology assessment for this policy (Canadian Agency for Drugs and Technologies in Health [CADTH], 2016). Their findings are consistent with previous findings. Therefore, no changes to the policy are warranted.

A new comprehensive systematic review included one RCT and three prospective pre-post studies that addressed the safety and efficacy of laparoscopic radiofrequency volumetric thermal ablation (RFVTA) using the Acessa System in the outpatient setting (Hayes, 2016). The overall low-quality evidence suggests a statistically significant short-term improvement in symptom severity and HRQoL after RFVTA. Adverse events were uncommon, and re-intervention occurred in up to 12 percent of cases. However, questions remaining about radiofrequency ablation are its comparative effectiveness to other surgical options (myomectomy in particular), treatment durability, and treatment efficacy by fibroid type. No policy changes are warranted at this time.

In the 2018 review, no new peer-reviewed literature was identified. A withdrawn guideline was deleted and another was added, however, it is in the process of being updated (National Guideline Clearinghouse,

2012).

Summary of clinical evidence:

Citation	Content, Methods, Recommendations
CADTH (2016) Uterine-preserving interventions for symptomatic uterine fibroids	Key points: <ul style="list-style-type: none"> • Systematic review of 10 RCTs and 16 non-randomized studies comparing myomectomy, UAE, uterine artery occlusion, magnetic resonance-guided focused ultrasound (MRgFU), or radiofrequency ablation to hysterectomy or each other. One RCT of laparoscopic radiofrequency ablation versus laparoscopic myomectomy (50 total patients). • Overall quality: low. Small sizes, imbalanced baseline patient characteristics, insufficient power. • All interventions improve quality of life and symptoms 6–24 months after treatment compared to baseline. RFA had a lower risk of peri-procedural complications, shorter hospital stay, and more future re-interventions than myomectomy.
Hayes (2016) Laparoscopic RFVTA using the Acessa System for uterine fibroids in the outpatient setting	Key points: <ul style="list-style-type: none"> • Systematic review of four studies (one RCT [Brucker, 2014], three prospective pre-post studies) reported in nine publications. The RCT compared RFVTA to laparoscopic myomectomy. • Overall quality: very low (uncontrolled studies) to moderate (RCT only). Limited by small sample size (31 to 135 participants per study), lack of a control group, limited follow-up, and substantial attrition. • RFVTA consistently reduced symptom severity and improved HRQoL using the Uterine Fibroid Symptom and HRQoL (UFS-QOL) questionnaire in the short term. • Reintervention rate: 0% to 12% included dilation and curettage for hypermenorrhea, UAE, hysterectomies, and myomectomies. • Incidence of pregnancy: eight pregnancies reported in three studies. • Adverse events are uncommon and included hypermenorrhea, vertigo, abdominal pain, urinary tract infection, abdominal wall injury, pelvic abscess, laceration of sigmoid colon, vaginal bleeding, uterine serosal burn, and severe hemorrhaging during cesarean section and early postpartum period. • Comparative effectiveness and treatment durability and efficacy by fibroid type remain unclear.
Fischer (2012) for the Ludwig Boltzmann Institute for Health Technology Assessment	Key points: <ul style="list-style-type: none"> • Systematic review of one RCT and five case series (352 total women). • Overall quality: low. Lack of control group in case series and inadequate control group (using high-intensity focused ultrasound) in the RCT. • RF is safe. Complication rates: major 0% to 9%; minor 0% to 34%; pain 2% to 13%; re-operation 0% to 4%. • RF improves both quality of life and symptoms 6–24 months after treatment compared to baseline values, but insufficient evidence of effectiveness relative to existing treatments.

References

Professional society guidelines/other:

American College of Obstetrics and Gynecology (ACOG). Uterine fibroids. FAQ074. May 2011. ACOG website. <http://www.acog.org/Patients/FAQs/Uterine-Fibroids>. Accessed March 8, 2018.

National Guideline Clearinghouse (NGC). Guideline summary: ACR Appropriateness Criteria® radiologic management of uterine leiomyomas. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); January, 2012. <https://www.guideline.gov>. Accessed March 8, 2018.

Vilos GA, Allaire C, Laberge P-Y, et al. The Management of Uterine Leiomyomas. *Journal of Obstetrics and Gynaecology Canada*. 37(2): 157 – 178.

Peer-reviewed references:

BusinessWire. Gynesonics Receives FDA Approval to Commence a Pivotal IDE Clinical Trial for the Newly-Designed Vizablate® System. October 22, 2014. BusinessWire website. www.businesswire.com/news/home/20141022005266/en/Gynesonics-Receives-FDA-Approval-Commence-Pivotal-IDE#VRW2qPnF_ws. Accessed March 8, 2018.

Chen S, Pitre E, Kaunelis D, Singh S. CADTH Rapid Response Reports. *Uterine-Preserving Interventions for the Management of Symptomatic Uterine Fibroids: A Systematic Review of Clinical and Cost-Effectiveness*. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health 2015© CADTH; 2016.

FDA. 510(K) Summary. 2000GI™ Electrosurgical Radiofrequency Ablation System. Halt Medical, Inc. (K094009). June 14, 2010. FDA website. www.accessdata.fda.gov/cdrh_docs/pdf9/K094009.pdf. Accessed March 8, 2018.

FDA. 510(K) Summary. Acesa System. Halt Medical, Inc. (K121858). November 5, 2012. FDA website. www.accessdata.fda.gov/cdrh_docs/pdf12/K121858.pdf. Accessed March 8, 2017.

Fischer S, Warmuth M. (2012). "Radiofrequenzablation bei Tumoren des Urogenitaltrakts (Nierenzellkarzinom, Prostatakarzinom, Leiomyome des Uterus). [Radiofrequency ablation of tumors of the urogenital tract (renal cell carcinoma, prostate cancer, uterine leiomyoma)]. Systematischer Review." Decision Support Dokument Nr. 59. Wien: Ludwig Boltzmann Institut for Health Technology Assessment website. <http://eprints.hta.lbg.ac.at/963/>. Accessed March 8, 2018.

Hayes Inc., Hayes Medical Technology Report. *Laparoscopic Radiofrequency Volumetric Thermal Ablation (Acesa System; Halt Medical Inc.) for Treatment of Uterine Fibroids*. Lansdale, Pa. Hayes Inc.; October 27, 2016.

Office of Women's Health (OWH). ePublication. Uterine Fibroids Fact Sheet. Department of Health and Human Services OWH website. February 6, 2017. <http://www.womenshealth.gov/publications/our-publications/fact-sheet/uterine-fibroids.html>. Accessed March 8, 2018.

CMS National Coverage Determinations (NCDs):

No NCDs identified as of the writing of this policy.

Local Coverage Determinations (LCDs):

No LCDs identified as of the writing of this policy.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

CPT Code	Description	Comments
58674	Laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency	

ICD-10 Code	Description	Comments
D25.0	Submucous leiomyoma of uterus	
D25.1	Intramural leiomyoma of uterus	
D25.2	Subserous leiomyoma of uterus	
D25.9	Leiomyoma of uterus, unspecified	

HCPCS Level II Code	Description	Comments
N/A		