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: May 19, 2017
Next Review Date: May 2018

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 Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania’s 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 Pennsylvania 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 Pennsylvania’s 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 Pennsylvania’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania’s clinical policies are not guarantees of payment.

Coverage policy

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

Limitations:

This clinical policy applies only to the use of RFA 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 (UAE).

**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 UAE (American College of Obstetricians and Gynecologists [ACOG], 2011). While less invasive, UAE has been associated with a relatively high proportion of cases that require another intervention, including hysterectomy.

RFA 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 2000G™ Electrosurgical Radiofrequency Ablation System and the Acessa System™ both by Halt 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 Pennsylvania 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 April 20, 2017. 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 RFA 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 RFA with 25 undergoing laparoscopic myomectomy (Brucker, 2014).

Limited evidence suggests RFA 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 RFA 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 RFA 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 RFA 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.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>CADTH (2016)</td>
<td>Key points:</td>
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</tbody>
</table>
### Uterine-preserving interventions for symptomatic uterine fibroids

- Systematic review of 10 RCTs and 16 non-randomized studies comparing myomectomy, UAE, uterine artery occlusion, magnetic resonance-guided focused ultrasound (MRgFU), or RFA to hysterectomy or each other. One RCT of laparoscopic RFA 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:**
- 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:**
- 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:**


**Peer-reviewed references:**


**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.

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<td>Laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency</td>
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