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 18, 2016
Next Review Date: May 2017

Policy contains:
- Radiofrequency ablation.
- Uterine fibroids.
- Leiomyoma.

Related policies:

CP# 12.03.02 Uterine artery embolization
CP# 12.03.03 Endometrial ablation

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’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 Prestige Health Choice 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. Prestige Health Choice’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. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of radiofrequency ablation (RF) for symptomatic uterine fibroids to be investigational and, therefore, not medically necessary.

Limitations:

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website can be accessed at http://ahca.myflorida.com/Medicaid/.

This clinical policy applies only to the use of RF 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.

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, in which fibroids, but not the uterus, are removed and uterine artery embolization (UAE). While less invasive, UAE has been associated with a relatively high proportion of cases that require another intervention, including hysterectomy.

Radiofrequency ablation (RF) of symptomatic uterine fibroids is a minimally invasive ablation method that destroys tumors by local application of heat. The United States Food and Drug Administration (FDA) has approved the 2000GI™ Electrosurgical Radiofrequency Ablation System and the Accessa System™ both by Halt Medical Inc., Brentwood, CA (FDA, 2010; FDA, 2012). In 2014, 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, CA) (BusinessWire, 2014).

Searches

Prestige Health Choice 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 25, 2016. Search terms were: “Radiofrequency Ablation” and “Uterine Fibroids,” “Ablation Techniques (MeSH),” “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 RF 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 RF with 25 undergoing laparoscopic myomectomy (Brucker, 2014).

Limited evidence suggests RF improves quality of life 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 RF 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 American College of Obstetrics and Gynecology (ACOG) nor the Society of Obstetricians and Gynaecologists of Canada recommend RF 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.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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</thead>
<tbody>
<tr>
<td>CADTH (2016)</td>
<td>Key points:</td>
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<tr>
<td>Uterine-preserving</td>
<td>Systematic review of 10 RCTs and 16 non-randomized studies comparing myomectomy, UAE, uterine artery occlusion (UAO), magnetic resonance-guided focused ultrasound (MRgFU) or RF to</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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<tr>
<td>Interventions for symptomatic uterine fibroids</td>
<td>hysterectomy or each other. One RCT of laparoscopic RF 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. RF had a lower risk of peri-procedural complications, shorter hospital stay and more future re-interventions than myomectomy.</td>
</tr>
<tr>
<td>Hayes (2014, updated 2015) Acessa System for uterine fibroids</td>
<td>Key points: • Systematic review of six single-arm studies and one RCT (n=31 to 135 for each study but total number of women not reported). • Overall quality: Low. Study design limitations. • RF reduced pain, heavy bleeding and other symptoms and improved quality of life. Longer term studies (2- or 3-year durations) demonstrated the durability of the treatment effect. • Larger RCTs are needed to confirm results.</td>
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<tr>
<td>Brucker (2014) RF versus laparoscopic myomectomy</td>
<td>Key Points: • RCT: n = 25 RF, n = 25 laparoscopic myomectomy. • Results: RF versus myomectomy – Hospital length of stay (10.0 ± 5.5 hours versus 29.9 ± 14.2 hours; P&lt;0.001) – Intraoperative blood loss (16 ± 9 mL versus 51 ± 57 mL; P&lt;0.001). – Proportion fibroids treated/excised for RF +22.8%.</td>
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<tr>
<td>Fischer (2012) for the Ludwig Boltzmann Institut for Health Technology Assessment</td>
<td>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 0-9%; minor 0-34%; pain 2-13%; re-operation 0-4%. • 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.</td>
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**Glossary**

**Hysterectomy** — Surgical removal of the uterus.

**Leiomyoma** — See Uterine fibroids.

**Myoma** — See Uterine fibroids.

**Myomectomy** — Surgical procedure to remove uterine fibroids.

**Radiofrequency ablation** — Minimally invasive technique that uses high-energy waves (heat) to destroy tissue.
**Uterine artery embolization** — Non-surgical treatment to block blood flow to the uterus.

**Uterine fibroids** — Benign growth of smooth muscle in the wall of the uterus.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**Clinical trials:**

Searched clinicaltrials.gov on April 25, 2016 using terms: “ablation OR myolysis OR radiofrequency uterine fibroid OR leiomyoma OR myoma” | Open Studies. Ten studies found, four relevant.


**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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<tr>
<td>0336T</td>
<td>Laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency</td>
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