Overview: Uterine leiomyomas (fibroids or myomas) are benign tumors. Since histologic confirmation of the clinical diagnosis is not necessary in most cases, and there is both growth and regression of fibroids, asymptomatic uterine leiomyomas can usually be followed without intervention. Research supports not treating asymptomatic fibroids. Treatments for symptomatic fibroids include medical management, hysterectomy, myomectomy, uterine artery embolization (UAE), radiofrequency ablation (RFA), laser ablation, cryoablation, and image-guided thermal ablation using ultrasonography or magnetic resonance imaging (MRI).

Policy and Coverage Criteria:

Harvard Pilgrim considers the following procedures medically necessary to treat symptomatic uterine fibroids:

- transcatheter uterine artery embolization (UAE);
- myomectomy

Harvard Pilgrim considers the following treatments for uterine fibroids experimental and investigational:

- laser ablation;
- cryoablation;
- cryomyolysis;
- image-guided thermal ablation using ultrasonography or magnetic resonance imaging (MRI); and MR-guided focused US (e.g. ExAblate, Acessa System)

Exclusions: N/A

Supporting Information:

1. Technology Assessment:

Uterine artery embolization (UAE), or uterine fibroid embolization (UFE), is a nonsurgical treatment for symptomatic uterine fibroids. UAE bilaterally reduces blood flow resulting in infarction of the fibroids. UAE is performed as an alternative to hysterectomy or myomectomy to control fibroid-related symptoms while sparing the normal myometrium.

Radiofrequency ablation (RFA) is a thermal ablative therapy where an electrode is applied to tissue resulting in frictional heat. The heat results in cell and tissue necrosis. This technique is used laparoscopically for tissue ablation within uterine fibroids.

Laser ablation is a technique where infrared laser energy is converted to heat in the fibroid resulting in cell and tissue necrosis. Use of laser thermoablative techniques have been limited by the inability to predict lesion size accurately or to visualize heating effects as the laser energy is applied.

Cryoablation is the thermal ablation method that causes cell death by rapid freezing followed by rapid thawing. Cryomyolysis involves a probe with a cooling agent that is applied to the myoma, causing coagulation of the supporting blood vessels. Through this procedure, the blood flow is diminished, resulting in necrosis. To date, cryomyolysis has not been FDA approved, but multiple studies have been done to investigate the safety and efficacy of this therapy.

Image-guided thermal ablation using ultrasonography or magnetic resonance imaging (MRI) is a technique where the clinician uses imaging (US or MRI) for guiding a thermal ablation procedure. MR-guided focused US (MRgFUS) is the therapeutic use of US waves to induce thermal effects, ablation, or thermocoagulation.
2. Literature Review:

Literature supports the use of myomectomy and hysterectomy as surgical interventions for uterine fibroids. UAE is a nonsurgical, less invasive alternative for the treatment of symptomatic fibroids. Alternative treatments such as radiofrequency, laser ablation, cryoablation, and thermal ablation have not been proven to be effective and safe.

UAE:

Hamoda et al (2015) conducted an intermediate (2-6 years) and long term (9-14 years) survey with women who underwent UAE to assess patient satisfaction and patterns of symptom progression. 81.7% of women who completed the intermediate questionnaire reported improvement in menstrual symptoms compared to 51.2% for the long-term questionnaire. The majority of women were satisfied with the embolization, however, satisfaction decreased over time. 28.8% required further surgical treatment following UAE.

Laios et al (2014) conducted a retrospective analysis of 118 patients who underwent UAE for treatment of symptomatic uterine fibroids. Results showed a significant reduction in mean fibroid volume, uterine size, and dominant fibroid size at 3 months and one year follow-up. Results also showed a significant improvement in symptoms and overall patient satisfaction. The authors concluded that UAE in the treatment of symptomatic fibroids is safe and effective.

Gupta et al (2014) reviewed seven randomized controlled trials of UAE versus any medical or surgical therapy for symptomatic uterine fibroids. Three trials compared UAE with abdominal hysterectomy, two trials compared UAE with myomectomy, and two trials compared UAE with either type of surgery (53 hysterectomies and 62 myomectomies). The authors found that there was no difference in satisfaction rates following UAE versus myomectomy or hysterectomy. UAE is a safe and minimally invasive alternative to surgery, however, patient selection and counseling are needed due to the higher risk of requiring further surgical intervention.

Ikink et al (2014) compared the effectiveness of magnetic-guided high-intensity focused ultrasound (MR-HIFU) with that of UAE for treatment of symptomatic uterine fibroids in 119 women (51 MR-HIFU; 68 UAE). Median symptom severity and HRQoL scores improved significantly in both groups at 3 month follow-up. UAE had a significantly stronger effect on symptom relief and HRQoL compared to MR-HIFU. Patients treated with MR-HIFU had a significantly higher risk (7.1 times higher) of reintervention within 12 months compared to UAE.

Froeling et al (2013) compared the long-term outcome after UAE versus MR-HIFU in 77 patients with symptomatic uterine fibroids. Symptom severity and HRQoL were assessed before treatment at long-term follow-up after UAE (median 61.9 months) and after MR-HIFU (median 60.7 months). Re-intervention was significantly lower after UAE (12.2%) compared to MR-HIFU (66.7%) at follow-up. Symptom Severity and HRQoL were significantly improved in the UAE group compared to the HR-HIFU group.

Ananthakrishnan et al (2013) reported the 5-year results from the REST trial. The trial included 157 participants who were randomized to either UAE or surgery (myomectomy or hysterectomy). MRI scans were conducted at baseline, 6 months, and 5 years to assess dominant fibroid diameter, uterine volume, total fibroid infarction, and new fibroid formation. At 5 years, the prevalence of new fibroid was significantly higher in myomectomy compared to UAE; 60% in the myomectomy group and 7% in the UAE group. There was a significant reduction in both uterine volume and dominant fibroid diameter between 6 months and 5 years after UAE.

RFA:

Berman et al (2014) conducted an analysis of the clinical success of 104 premenopausal women who received radiofrequency volumetric thermal ablation (RFVTA) for uterine myomas 36 months following treatment. Results showed a significant improvement in symptom severity and HRQoL from baseline to 36 months. There was a repeat intervention rate of 11% at 36 months. The authors concluded that RFVTA of uterine myomas result in sustained relief from myoma symptoms and continued improvement in HRQoL.

Brucker et al (2014) compared the mean hospital discharge times and perioperative outcomes for RFVTA of fibroids and laparoscopic myomectomy (LM). The results showed a significantly shorter hospital stay, the treatment of more fibroids, and less intraoperative blood loss compared to LM.

Chudnoff et al (2013) conducted a prospective trail of 135 premenopausal symptomatic women with uterine fibroids who underwent outpatient laparoscopic ultrasound-guided RFVTA. Results showed a significant decrease in menstrual blood loss from baseline at 3, 6, and 12 month follow-ups. There was a significant improvement in symptom severity and HRQoL from baseline to 12 months. The authors concluded that RFVTA of myomas is well tolerated and results in rapid recovery, high patient satisfaction, improved QoL, and effective symptom relief.
Laser ablation:
Law et al (2000) performed laser ablation in 12 symptomatic women with uterine fibroids. At 3 month follow-up, measurements showed a mean decrease in fibroid volume of 37.5%. The authors concluded that this novel minimally invasive approach offers an alternative to surgery for women with fibroids, but longer follow-up is needed to ascertain maximal fibroid shrinkage and to compare outcome with traditional surgery.

Cryoablation:
Pansky et al (2009) conducted a multicenter pilot case series to develop a safe and effective cryoablation technique for the treatment of uterine fibroids. The results showed a median fibroid volume reduction of 43.3% in 19 patients and 66.4% in 15 patients at 6 and 12 months. An improvement of 61% and 66.7% at 6 and 12 months was seen using a validated Uterine Fibroid Symptom and Quality of Life questionnaire. Patients experienced improvement of bleeding and fibroid bulk symptoms. The authors concluded that the pilot data indate that uterine fibroid cryoablation is a safe and effective minimally invasive alternative to treat symptomatic uterine fibroids.

Sakuhara et al (2006) evaluated the feasibility and effectiveness of MR-guided percutaneous cryoablation for uterine fibroids in 6 symptomatic women. Results showed a reduction in tumor size in all patients who were treated with a mean volume reduction of 40.3% at 6 weeks postoperatively, and 79.4% at 9-12 months. All patients exhibited a fever postoperatively. One patient required surgical drainage for an abscess in the probe channel, and one patient had transient liver damage. Subjective symptoms improved in 5 of the women and none of the women complained of new symptoms following cryoablation during follow-up. The authors concluded that MR-guided percutaneous cryoablation is a feasible and effective treatment for uterine fibroids.

Image-guided thermal ablation using ultrasonography or magnetic resonance imaging (MRI):
Himabindu et al (2014) conducted a prospective study treating 32 women who had symptomatic uterine fibroids with magnetic resonance guided focused ultrasound sonication (MRgFUS). Symptom severity was assessed pre and post treatment at one, three, and six months. Fibroid volumes were compared pre and post treatment and at six month follow-up. The results showed a significant reduction in symptom severity scores at one, three, and six months. Significant reduction in fibroid volume was seen at six months compared to pretreatment. The authors concluded that MRgFUS is relatively a safe and effective non invasive treatment for uterine fibroids, however, its long term efficacy is yet to be tested and compared with other minimally invasive treatments.

Gorny et al (2014) conducted a retrospective follow-up of 138 patients treated with MRgFUS of uterine fibroids to assess long-term outcomes. The patients were not a part of a clinical study and were followed through retrospective review of their medical records and telephone interviews. Additional treatments after MRgFUS were 19% and 23% at 36 and 48 months. The results showed that physician predictions of treatment success had a significant predictive value.

Codes:

Covered CPT codes:

37243 - Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
37244 - Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation

Noncovered CPT codes:

0336T - Laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency
0071T - Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue
0072T - Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue
References:

4. Stewart, EA. Epidemiology, clinical manifestations, diagnosis and natural history of uterine leiomyomas (fibroids). In: UpToDate, Post, TW (ed), Waltham, MA, 2015.

**Summary of Changes**

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<thead>
<tr>
<th>Date</th>
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