GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
Uterine fibroids (also called leiomyomata or myomas) are benign tumors of the myometrium, the smooth muscle layer of the uterus. In the sixth decade of life, the prevalence of fibroids is almost 70% in Caucasian women and 80% in black women. Fibroids can produce pain, pressure, frequent and heavy bleeding, infertility, urinary frequency, dyspareunia (pain during intercourse), and miscarriage. In the United States, fibroids are the most common indication for hysterectomy.

Treatments for symptomatic fibroids include medical management, hysterectomy, myomectomy (removal of the fibroids while leaving the uterus in situ), radiofrequency ablation, uterine artery embolization or occlusion, laser ablation, cryoablation, and image-guided thermal ablation using ultrasonography or magnetic resonance imaging (MRI). Medical treatments provide only short-term relief. Myomectomy may be performed as an open procedure or using a hysteroscope or laparoscope, depending on the location of the fibroids producing symptoms. Complications of treatments for fibroids include hemorrhage, abdominal adhesions, and interruption of uterine integrity.

Uterine Artery Occlusion: This is an angiographic procedure in which small particles or microspheres are used to occlude the uterine arteries, with the goal of depriving fibroids of their blood supply, causing them to shrink in size. The objective is to relieve the symptoms associated with fibroids and to preserve childbearing potential.

Magnetic Resonance Imaging (MRI)-Guided Cryoablation: This procedure is also known as interventional MRI (I-MRI) cryoablation. It uses a specially designed, I-MRI scanner to locate the fibroids and guide their cryosurgical destruction through a transabdominal percutaneous approach. The published evidence on MRI-guided cryoablation for uterine fibroids is very limited, as the procedure has been evaluated in very few patients. The long-term outcomes and overall health benefits remain unknown. Further long-term studies on larger samples published in peer-reviewed medical literature are necessary to demonstrate the safety and efficacy of this technology.

Magnetic Resonance Imaging (MRI)-Guided Focused Ultrasound (FUA): This procedure combines real-time MRI-guidance with high-intensity focused ultrasound for the noninvasive thermal ablation of uterine fibroids. Tumor ablation is performed by focusing a collection of ultrasonic beams to increase sonic beam intensity at a point deep within the tissue to cause thermal coagulation while sparing normal tissues. The procedure is also referred to as MRgFUS. An example of such device used for this purpose includes, but may not be limited to, the ExAblate 2000. Further studies are needed to determine the long-term efficacy of this procedure and to evaluate the efficacy and safety of this procedure relative to other treatment options for uterine fibroids.

Laparoscopic Ultrasound-Guided Radiofrequency Ablation: This minimally invasive procedure uses a laparoscopic ultrasound probe to determine the location and size of fibroids. Then a small electrode array delivers radiofrequency energy to destroy the fibroids. An example of such device used for this purpose includes, but may not be limited to, the Acessa System. Further studies are needed to determine the long-term efficacy of this procedure and to evaluate the efficacy and safety of this procedure relative to other treatment options for uterine fibroids.

Transcervical Ultrasound-Guided Radiofrequency Ablation: This minimally invasive procedure destroys fibroids using a transcervical radiofrequency ablation device under integrated, real-time, intrauterine ultrasound imaging guidance. Further studies are needed to determine the long-term efficacy of this procedure and to evaluate the efficacy and safety of this procedure relative to other treatment options for uterine fibroids.

Laparoscopic Power Morcellation Warning
On November 24, 2014 the U.S. Food and Drug Administration (FDA) issued a Safety Communication recommending that manufacturers of laparoscopic power morcellators with a general indication or a specific gynecologic indication prominently include the following black box warning and contraindications in their product labeling:
WARNING: Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.

CONTRAINdications:
- Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.
- Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are peri- or post-menopausal, or are candidates for en bloc tissue removal, for example through the vagina or via a mini-laparotomy incision.

POLICY

Non-covered uterine fibroid treatments for all product lines:
- Myomectomy or hysterectomy using power morcellation (C1782)
- MRI-guided cryoablation
- MRI-guided focused ultrasound ablation (FUA) (e.g., ExAblate2000) (0071T, 0072T)
- Transcervical ultrasound-guided radiofrequency ablation (0404T)

Uterine artery occlusion (37243) does not require prior authorization for all product lines.

Laparoscopic ultrasound-guided radiofrequency ablation of uterine fibroids (e.g., Acessa System) (58674) is non-covered for HMO, PPO, Individual Marketplace, & Elite.

Laparoscopic ultrasound-guided radiofrequency ablation of uterine fibroids (e.g., Acessa System) (58674) does not require prior authorization for Advantage.

Paramount considers myomectomy or hysterectomy using power morcellation experimental and investigational for the removal of uterine fibroids because its safety and effectiveness has not been established.

Paramount considers the following treatments for uterine fibroids experimental and investigational because their safety and effectiveness have not been established:
- Uterine artery occlusion
- MRI-guided cryoablation
- MRI-guided focused ultrasound ablation (e.g., ExAblate2000)
- Transcervical ultrasound-guided radiofrequency ablation

Paramount considers uterine artery occlusion (37243) medically necessary for patients with confirmed, symptomatic uterine fibroids who would like an alternative to surgical treatment or are not suitable surgical candidates and who are not concerned about preserving their childbearing potential or sparing uterine integrity.

HMO, PPO, Individual Marketplace, Elite

Paramount considers laparoscopic ultrasound-guided radiofrequency ablation of uterine fibroids (e.g., Acessa System) (58674) experimental and investigational because its safety and effectiveness have not been established.

Advantage

While there is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcomes of laparoscopic ultrasound-guided radiofrequency ablation of uterine fibroids (e.g., Acessa System) (58674), per ODM guidelines it is covered for Advantage members.

CODING/BILLING INFORMATION

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0071T</td>
<td>Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue</td>
</tr>
<tr>
<td>0072T</td>
<td>Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue</td>
</tr>
<tr>
<td>0336T</td>
<td>Laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency (Deleted effective 12/31/16)</td>
</tr>
<tr>
<td>0404T</td>
<td>Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency (Effective 01/01/2016)</td>
</tr>
</tbody>
</table>
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.

Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency (Effective 01/01/17 new code).

**HCPCS CODES**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>C1782</td>
<td>Morcellator</td>
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**TAWG REVIEW DATES:** 08/20/2015, 02/26/2016, 03/24/2017, 03/22/2018

**REVISION HISTORY EXPLANATION**

08/20/15: Policy created to reflect most current clinical evidence per TAWG.

02/26/16: Changed title from Radiofrequency Ablation of Uterine Fibroids to Uterine Fibroid Surgical Treatments. Added effective 01/01/16 new code 0404T. Added codes 0071T, 0072T, 37243, C1782. Policy reviewed and updated to reflect most current clinical evidence per TAWG.

03/24/17: Deleted effective 12/31/16 code 0336T that was covered without prior authorization for Elite per CMS guidelines, and non-covered for HMO, PPO, Individual Marketplace, & Advantage. Added effective 01/01/17 new code 58674 as covered without prior authorization for Advantage per ODM guidelines, and non-covered for HMO, PPO, Individual Marketplace, & Elite. Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

03/22/18: Uterine artery occlusion (37243) is now covered without prior authorization for all product lines. Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

**REFERENCES/RESOURCES**

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid [http://jfs.ohio.gov/](http://jfs.ohio.gov/)
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.