Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Uterine Fibroid Surgical Treatments

Policy Number: PG0344
Last Review: 11/01/2021

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE:

X Professional
X Facility

DESCRIPTION:

Uterine fibroids (also called leiomyomata or myomas) are noncancerous tumors that develop from the smooth muscular tissue of the uterus (myometrium). Uterine fibroids are among the most common conditions affecting women in the reproductive years. 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). 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 Embolization (UAE): 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. UAE also can be referred to as uterine fibroid embolization (UFE).

In 2019, the American College of Obstetricians and Gynecologists reaffirmed its 2008 position on alternatives to hysterectomy in the management of leiomyomas. Recommendations based on good and consistent scientific evidence were that abdominal myomectomy is a safe and effective treatment for women with symptomatic leiomyomas and that uterine artery embolization is a safe and effective option for appropriately selected women who want to retain their uteri.

Cryoablation:

Freezing fibroids is known as cryoablation. With this technology, freezing temperatures are delivered to the endometrium via a cryoprobe during laparoscopy or hysteroscopy. An example of such device used for this purpose includes, but may not be limited to, the Cerene Cyroablation System.

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.

- In 2012, the Acessa™ System (Acessa Health, formerly Halt Medical) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for percutaneous laparoscopic coagulation and ablation of soft tissue and treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance (K121858). The technology was previously approved in 2010, at which time it was called the Halt 2000GI™ Electrosurgical Radiofrequency Ablation System. In 2014, the ultrasound guidance system received marketing clearance from the FDA (K132744). FDA product code: GEI.
- In 2018, the third generation Acessa™ ProVu System® was cleared for marketing by the FDA through the 510(k) process for use in percutaneous laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. (K181124). FDA product code: HFG.

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.

- In 2018, the Sonata® Sonography-Guided Transcervical Fibroid Ablation System (Gynesonics, Inc., Redwood City, CA) was cleared for marketing by the FDA through the 510(k) process for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids (K173703). The Sonata system was previously known as Vizablate. FDA product codes: KNF, ITX, and IYO.

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:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Coverage for selective ablative techniques of myolysis as a treatment of uterine fibroids is considered to be medically necessary when the medical criteria and guidelines listed below are met.

Effective 11/1/2021 - Laparoscopic ultrasound-guided radiofrequency ablation of uterine fibroids (e.g., Acessa System) (58674) does not require prior authorization for all product lines.

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

Paramount Commercial Plans, Medicare Advantage Plans and Paramount Medicaid Advantage

- **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 (e.g., Sonata® System)(0404T) is not covered for all product lines. There is insufficient evidence in the published peer-reviewed literature to support the safety and effectiveness of radiofrequency ablation and the use of the Sonata® Systems for the treatment of uterine fibroids.**

Non-participating providers are required to obtain prior authorization BEFORE any services are rendered.

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Surgery, including hysterectomy and various myomectomy procedures, is considered the criterion standard treatment for symptom resolution.

The following procedures are covered when conservative medical management, typically hormonal therapies, has failed to control the symptoms attributable to uterine fibroids:

- Myomectomy—the surgical removal of fibroids while leaving the uterus in place.
- Hysterectomy— the surgical removal of the uterus. The ovaries may or may not be removed.
- Uterine artery embolization— a non-surgical procedure in which the blood vessels to the uterus are blocked, stopping the blood flow that allows fibroids to grow

Persistence of one or more symptoms directly attributable to uterine fibroids are supported by the following:

- Excessive menstrual bleeding (menorrhagia) as evidenced by either profuse or prolonged bleeding, or anemia due to acute or chronic blood loss; or,
- Pelvic discomfort caused by myomata, manifesting as:
    - acute severe pain; or
    - chronic lower abdominal pain; or
    - dyspareunia; or
    - low back pressure; or
    - bladder pressure with urinary frequency not due to urinary tract infection.

The use of laparoscopic radiofrequency ablation (e.g., Acessa™) of uterine fibroids as an alternative to hysterectomy or myomectomy is considered medically necessary when:

- Persistence of one or more symptoms directly attributed to uterine fibroids (i.e., excessive menstrual bleeding (menorrhagia), pelvic pain, pressure or discomfort, urinary symptoms referable to compression of the ureter or bladder, and/or dyspareunia (painful or difficult sexual relations)), and
- Symptoms have been persistent (lasting three consecutive months or greater in duration) despite medical management (eg, hormonal therapy, NSAIDs), and
- Evidence of uterine fibroids via imaging-confirmed presence, and

- Uterine size does not exceed 16 weeks gestation, and
- Pre-menopausal state with symptomatic fibroids in members who want to avoid a hysterectomy, desires uterine sparing procedure, or
- Members who have contraindications to general anesthesia

Laparoscopic radiofrequency ablation (e.g., Acessa™) are considered exclusions for all situations other than those specified above, not an all-inclusive listing:

- When there has been a diagnosis of cancer (or pre-cancerous lesions) anywhere in the pelvis, or
- In members who are diagnosed with or at risk for leiomyosarcoma, or
- In members with acute pelvic inflammatory disease, or
- In members with abnormal pap smear test results, or
- In members who are in post-menopausal state, or
- The member has only Type 0 (pedunculated intracavitary, submucosal) or Type 7 (subserosal pedunculated) fibroid.
- ❖ The use of all other laparoscopic or percutaneous ablation techniques in combination with imaging guidance as a treatment of uterine fibroids are considered investigational and not medically necessary, including but not limited to lasers, bipolar electrodes, interstitial thermotherapy, cryotherapy.

Uterine artery occlusion (37243) is considered medically necessary as an alternative to hysterectomy or myomectomy for the treatment of uterine fibroids when:

- Members have confirmed, symptomatic uterine fibroids who would like an alternative to surgical treatment; or
- In members, not suitable surgical candidates; and
- Members are not concerned about preserving their childbearing potential or sparing uterine integrity.

Fibroid removal with power morcellation is considered medically necessary for the following indications in women without known or strongly suspected uterine cancer:

- Premenopausal women who wish to maintain fertility and who have no risk factors for uterine sarcoma (e.g., history of 2 or more years of tamoxifen therapy, history of pelvic irradiation, history of childhood retinoblastoma, Lynch syndrome, or personal history of hereditary leiomyomatosis and renal cell carcinoma syndrome); or
- Women with comorbidities (e.g., cardiovascular, renal, hepatic, pulmonary, endocrine, or morbid obesity) where surgical alternatives to fibroid removal with power morcellation (hysterectomy without power morcellation, uterine artery embolization) pose an unacceptable risk.

❖ In all cases, the member must be informed of alternative procedures for fibroids and the risks of power morcellation in spreading unsuspected cancerous tissue beyond the uterus.

❖ Myomectomy or hysterectomy using power morcellation for the removal of uterine fibroids for all other indications is considered experimental and investigational 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, not all-inclusive listing:

- Acupuncture
- Bipolar electrodes
- Cryomyolysis
- Cryoablation of fibroids (eg, Cerene Cryoablation System)
- Interstitial thermotherapy,YAG lasers
- MRI-guided cryoablation
- MRI-guided focused ultrasound ablation (MrgFus)(e.g., ExAblate2000) (0071T, 0072T)
- Myomectomy or hysterectomy using power morcellation (C1782)
- Transcervical radiofrequency ablation (eg, Sonata System) (0404T)

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	
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
37617	Ligation , major artery (eg, post-traumatic, rupture); abdomen
58140	Myomectomy, excision of fibroid tumor(s) of uterus, 1 to 4 intramural myoma(s) with total weight of 250 g or less and/or removal of surface myomas; abdominal approach
58145	Myomectomy, excision of fibroid tumor(s) of uterus, 1 to 4 intramural myoma(s) with total weight of 250 g or less and/or removal of surface myomas; vaginal approach
58146	Myomectomy, excision of fibroid tumor(s) of uterus, 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g, abdominal approach
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s);
58152	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s); with colpo-urethrocystopexy (e.g., Marshall-Marchetti-Krantz, Burch)
58180	Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)
58200	Total abdominal hysterectomy, including partial vaginectomy, with para-aortic and pelvic lymph node sampling, with or without removal of tube(s), with or without removal of ovary(s)
58210	Radical abdominal hysterectomy, with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy), with or without removal of tube(s), with or without removal of ovary(s)
58240	Pelvic exenteration for gynecologic malignancy, with total abdominal hysterectomy or cervicectomy, with or without removal of tube(s), with or without removal of ovary(s), with removal of bladder and ureteral transplantations, and/or abdominoperineal resection of rectum and colon and colostomy, or any combination thereof
58260	Vaginal hysterectomy, for uterus 250 g or less;
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
58263	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s), with repair of enterocele
58267	Vaginal hysterectomy, for uterus 250 g or less; with colpo-urethrocystopexy (Marshall-Marchetti-Krantz type, Pereyra type) with or without endoscopic control
58270	Vaginal hysterectomy, for uterus 250 g or less; with repair of enterocele
58275	Vaginal hysterectomy, with total or partial vaginectomy;
58280	Vaginal hysterectomy, with total or partial vaginectomy; with repair of enterocele
58285	Vaginal hysterectomy, radical (Schauta type operation)
58290	Vaginal hysterectomy, for uterus greater than 250 g;
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58292	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s), with repair of enterocele
58293	Vaginal hysterectomy, for uterus greater than 250 g; with colpo-urethrocystopexy (Marshall-Marchetti-Krantz type, Pereyra type) with or without endoscopic control
58294	Vaginal hysterectomy, for uterus greater than 250 g; with repair of enterocele
58353	Endometrial ablation, thermal, without hysteroscopic guidance
58356	Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less;
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g;
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58545	Laparoscopy, surgical, myomectomy, excision; 1 to 4 intramural myomas with total weight of 250 g or less and/or removal of surface myomas

58546	Laparoscopy, surgical, myomectomy, excision; 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g
58548	Laparoscopy, surgical, with radical hysterectomy, with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy), with removal of tube(s) and ovary(s), if performed
58550	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less;
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g;
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58561	Hysteroscopy, surgical; with removal of leiomyomata
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less;
58575	Laparoscopy, surgical, total hysterectomy for resection of malignancy (tumor debulking), with omentectomy including salpingo-oophorectomy, unilateral or bilateral, when performed
58578	Unlisted laparoscopy procedure, uterus [considered experimental/investigational when specified as laparoscopic ablation by laser, bipolar electrodes, interstitial thermotherapy, cryotherapy]
58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency
58999	Unlisted procedure, female genital system (nonobstetrical) [considered experimental/investigational when specified as laparoscopic ablation by laser, bipolar electrodes, interstitial thermotherapy, cryotherapy]
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
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency (Effective 01/01/2016)
HCPCS CODES	
C1782	Morcellator

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 08/20/2015

Date	Explanation & Changes
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)
12/21/2020	• Medical policy placed on the new Paramount Medical Policy Format

11/01/2021	• Policy reviewed and updated to reflect most current clinical evidence
	• Coverage criteria indicated for;
	  ○ Laparoscopic ultrasound-guided radiofrequency ablation of uterine fibroids (e.g., Acessa System) (58674)
	  ○ Uterine artery occlusion (37243)

	• Laparoscopic ultrasound-guided radiofrequency ablation of uterine fibroids (e.g., Acessa System) (58674) does not require prior authorization for all product lines • Uterine artery occlusion (37243) does not require prior authorization for all product lines • Transcervical ultrasound-guided radiofrequency ablation (e.g., Sonata® System)(0404T) is not covered for HMO, PPO, Individual Marketplace and Elite/ProMedica Medicare Plan and Advantage product lines
02/23/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/
Industry Standard Review

Hayes, Inc., https://www.hayesinc.com/

Industry Standard Review