Priority Health

MEDICAL POLICY No. 91573-R6

UTERINE FIBROID TREATMENT

Effective Date: September 1, 2025	**Review Dates: 6/10, 6/11, 6/12, 6/13, 8/14, 8/15, 8/16, 8/17, 8/18, 11/18, 11/19, 11/20, 5/21, 5/22, 8/22, 8/23, 8/24, 8/25**
Date Of Origin: June 9, 2010	**Status: Current**

Related policies: Menorrhagia Treatment medical policy #91575

Summary of Changes

Addition:

- New exclusion for Sonata - Member with an unusually short endometrial cavity (< 4.5 cm fundus-to-external opening of cervix).

Clarification:

- Formatting.

I. POLICY/CRITERIA

A. The following procedures are covered when conservative medical management (e.g., hormonal therapies), has failed to control the symptoms attributable to uterine fibroids:

1. Uterine artery embolization
2. Myomectomy
3. Hysterectomy

B. Laparoscopic ultrasound-guided radiofrequency ablation (e.g., Acessa) for the treatment of uterine fibroids as an alternative to hysterectomy or myomectomy is medically necessary when one or more of the following are met:

1. An abdominally palpable fibroid.
2. Bulk-related symptoms (e.g., pelvic pain, pressure or discomfort, urinary symptoms related to compression of the ureter or bladder, and/or dyspareunia) resulting directly from the fibroid.
3. Dyspareunia (painful or difficult sexual relations) resulting directly from the fibroid.
4. Gastrointestinal symptoms related to compression of the bowel (e.g., constipation, bloating) resulting directly from the fibroid.
5. Severe menorrhagia causing anemia resulting directly from the fibroid (e.g., not resulting from hyperplasia, atypia, or cancer).

C. The use of laparoscopic ultrasound-guided radiofrequency ablation (e.g., Acessa) of uterine fibroids is excluded if any of the following applies:

1. The member has only Type 0 (pedunculated intracavitary, submucosal) or Type 7 (subserosal pedunculated) fibroid.

2. The member has risk factors for leiomyosarcoma or malignancy.
3. Pre-menopausal members seeking future fertility.

D. Transcervical ultrasound-guided radiofrequency ablation (e.g., Sonata System) for the treatment of uterine fibroids as an alternative to hysterectomy or myomectomy is medically necessary when one or more of the following are met:

1. An abdominally palpable fibroid less than 7cm.
2. Bulk-related symptoms (e.g., pelvic pain, pressure or discomfort, urinary symptoms related to compression of the ureter or bladder, and/or dyspareunia) resulting directly from the fibroid.
3. Dyspareunia (painful or difficult sexual relations) resulting directly from the fibroid.
4. Gastrointestinal symptoms related to compression of the bowel (e.g., constipation, bloating) resulting directly from the fibroid.
5. Severe menorrhagia causing anemia resulting directly from the fibroid (e.g., not resulting from hyperplasia, atypia, or cancer).
6. The provider performing transcervical ultrasound-guided radiofrequency ablation (e.g., Sonata) must be a board-certified obstetrician-gynecologist who has received training and certification in the use of the device from Gynesonics; certification should be made available if requested by Priority Health.

E. The use of transcervical ultrasound-guided radiofrequency ablation (e.g., Sonata) of uterine fibroids is excluded if any of the following applies:

1. The member has only Type 0 (pedunculated intracavitary, submucosal) or Type 7 (subserosal pedunculated) fibroid.
2. The member has risk factors for leiomyosarcoma or known or suspected gynecologic malignancy or premalignant disorders such as atypical endometrial hyperplasia.
3. Pre-menopausal members seeking future fertility.
4. The member has an active pelvic infection.
5. The presence of one or more intra-tubal (intrauterine) implants for sterilization.
6. The presence of an intrauterine (IUD), unless removed prior to the introduction of the Sonata device.
7. The member is currently pregnant.
8. Member with an unusually short endometrial cavity (< 4.5 cm fundus-to-external opening of cervix (os))

F. All other indications are considered experimental and investigational.

G. All other laparoscopic, transcervical, 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:

1. Lasers
2. Bipolar electrodes
3. Interstitial thermotherapy
4. Cryotherapy.

MRI guided focused ultrasound (MRgFUS) (e.g., ExAblate) is considered to be experimental and investigational. H. Fibroid removal with power morcellation is considered medically necessary for the following indications in women without known or strongly suspected uterine cancer:

1. 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*
2. 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.
3. 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.

I. 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.

II. GOVERNMENT REGULATIONS

CMS Coverage Determinations	Title and Number
National Coverage Determinations (NCDs)	N/A
Local Coverage Determinations	N/A

III. MEDICAL OR PROFESSIONAL SOCIETY GUIDELINES/POSITION STATEMENTS

Medical or Professional Society	Recommendation
American College of Obstetricians and Gynecologists (ACOG)	Management of Symptomatic Uterine Leiomyomas

American College of Obstetricians and Gynecologists (ACOG)	ACOG practice bulletin. Alternatives to hysterectomy in the management of leiomyomas.

IV. FDA

Device	PMA Number	Notice Date	Indication
Acessa ProVu System	K181124	09/28/2018	The Acessa ProVu System is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. The Acessa ProVu System includes optional electromagnetic guidance for enhancing the ultrasonic image of the Acessa ProVu Handpiece and for predicting its future path on a computer monitor screen which also shows the ultrasound B-scan image.
Acessa Guidance System	K132744	05/27/2014	The Acessa Guidance System is indicated for enhancing the ultrasonic image of the Acessa Handpiece and for predicting its future path on a computer monitor screen which also shows the image of a B-scan (or similar display) of a medical ultrasound imaging system. The device is intended as an optional accessory for use during the Acessa System procedure.
Acessa Guidance Handpiece	K132184	04/28/2014	The Acessa Guidance Handpiece is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance.
Exablate Model 2100V1, Exablate Prostate System, Exablate MRgFUS, Exablate 2100V1 Type 3.0	K231378	10/30/2023	The Exablate Prostate System is indicated for endorectal MR-Guided Focused Ultrasound (MRgFUS) ablation of Prostatic Tissue.
Exablate Prostate System	K212150	11/23/2021	The Exablate Prostate System is indicated for endorectal MR-Guided Focused Ultrasound (MRgFUS) ablation of Prostatic Tissue.
Sonata Transcervical Fibroid Ablation System 2.2	K250705	04/02/2025	The Sonata® Transcervical Fibroid Ablation System is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine

			fibroids, including those associated with heavy menstrual bleeding.
Sonata Transcervical Fibroid Ablation System 2.2 (SONATA2-220)	K233848	12/21/2023	The Sonata Transcervical Fibroid Ablation System is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.
Sonata Transcervical Fibroid Ablation System 2.2	K222304	11/08/2022	The Sonata@ Transcervical Fibroid Ablation System 2.2 is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.
Sonata Transcervical Fibroid Ablation System 2.2	K211535	06/17/2021	The Sonata® Transcervical Fibroid Ablation System is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.
Sonata® Sonography-Guided Transcervical Fibroid Ablation System 2.1	K193516	05/04/2020	The Sonata® Sonography-Guided Transcervical Fibroid Ablation System 2.1 is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.
Sonata Sonography-Guided Transcervical Fibroid Ablation System	K173703	08/15/2018	The Sonata® Sonography-Guided Transcervical Fibroid Ablation System is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.

V. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

VI. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***

- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

IV. DESCRIPTION

Uterine fibroids, also known as leiomyomas or myomata, are benign tumors of the uterus. Uterine fibroids can be completely asymptomatic or can cause a variety of symptoms including abnormal uterine bleeding, pelvic pain and possible reproductive failure. Relief of symptoms is the major goal in management of women with significant symptoms. The type and timing of any intervention should be individualized, based upon factors such as size, location, symptom severity, age, reproductive plans and obstetrical history. There are both non-surgical and surgical treatment options of similar efficacy and therefore individual consideration and discussion regarding the best treatment option is recommended.

Conservative medical management including drug therapy is often the first option for treatment of women with fibroids. Medications may reduce the heavy bleeding and painful periods that fibroids sometimes cause. Unfortunately, drug therapy may not prevent the growth of fibroids and therefore in some cases surgery may be needed.

Laparoscopic power morcellators are medical devices used during different types of minimally invasive surgeries (FDA, 2014). These can include certain procedures to treat uterine fibroids (e.g., hysterectomy and myomectomy). Morcellation refers to the division of tissue into smaller pieces or fragments and is often used during laparoscopic surgeries to facilitate the removal of tissue through

small incision sites. Recent clinical information suggested that laparoscopic power morcellation poses a risk of spreading unsuspected cancerous tissue (e.g., uterine sarcomas) to travel beyond the uterus (FDA, 2014).

FDA issued a safety communication in November 2014, "Based on an FDA analysis of currently available data, we estimate that approximately 1 in 350 women undergoing hysterectomy or myomectomy for the treatment of fibroids is found to have an unsuspected uterine sarcoma, a type of uterine cancer that includes leiomyosarcoma. At this time, there is no reliable method for predicting or testing whether a woman with fibroids may have a uterine sarcoma.

If laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma, there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient's long-term survival. While the specific estimate of this risk may not be known with certainty, the FDA believes that the risk is higher than previously understood.

Because of this risk and the availability of alternative surgical options for most women, the FDA is warning against the use of laparoscopic power morcellators in the majority of women undergoing myomectomy or hysterectomy for treatment of fibroids.

Limiting the patients for whom laparoscopic morcellators are indicated, the strong warning on the risk of spreading unsuspected cancer, and the recommendation that doctors share this information directly with their patients, are part of FDA guidance to manufacturers of morcellators. The guidance strongly urges these manufacturers to include this new information in their product labels.

MRI guided focused ultrasound (MRgFUS) (e.g., ExAblate) uses ultrasound waves, directed at the fibroids through the skin with the help of magnetic resonance imaging, are used to destroy fibroids.

Laparoscopic ultrasound-guided radiofrequency ablation (e.g., Acessa) is a minimally invasive procedure wherein small incisions are made in the abdomen to place a camera, an ultrasound, and the ablation device. Under ultrasound guidance the ablation device is inserted into the fibroids. The heat produced causes tissue damage and the fibroids shrink over the weeks to months after the procedure. Evidence suggests that RFVTA generally resulted in statistically significant improvements in symptom severity from baseline. Acessa offers an uterine-sparing treatment modality for the treatment of fibroids, however, there is insufficient data to evaluate the safety and effectiveness of the Acessa procedure in women who wish to maintain fertility and achieve a future pregnancy. Physicians should counsel the patient regarding the potential risks and benefits.

The Sonata Sonography-Guided Transcervical Fibroid Ablation System is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding. The system uses ultrasound for visualization and radiofrequency energy for ablative therapy. Both functions are combined in a single device which includes an intrauterine ultrasound probe and a single-use RFA handpiece. The system uses a transcervical approach without incisions or material uterine distension and is therefore uterine sparing. However, the perinatal and post-partum outcomes for women who desire to become pregnant is unknown.

V. CODING INFORMATION

ICD-10 Codes that may apply*:*

D25.0 Submucous leiomyoma of uterus
D25.1 Intramural leiomyoma of uterus
D25.2 Subserosal leiomyoma of uterus
D25.9 Leiomyoma of uterus, unspecified

CPT/HCPCS Codes:

37243 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction

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
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
58674 Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency
58580 Transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency
C1782 Morcellator

Not Covered:
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

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Laparoscopic (e.g., Acessa) ultrasound-guided radiofrequency ablation

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Transcervical ultrasound-guided radiofrequency ablation

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