NO. 91573

UTERINE FIBROID TREATMENT

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Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This policy addresses the medical necessity of surgical and minimally invasive treatments for symptomatic uterine fibroids (leiomyomas) when symptoms persist despite conservative medical management.

Related policies:

- Menorrhagia Treatment - #91575

I. MEDICAL NECESSITY CRITERIA

Uterine fibroid treatment may be considered medically necessary when criteria are met.

INCLUSIONS:

A. The following procedures, 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 when one or more of the following are met:

1. 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.
2. Dyspareunia (painful or difficult sexual relations) resulting directly from the fibroid.
3. Gastrointestinal symptoms related to compression of the bowel (e.g., constipation, bloating) resulting directly from the fibroid.
4. Severe menorrhagia causing anemia resulting directly from the fibroid (e.g., not resulting from hyperplasia, atypia, or cancer).

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

1. Fibroid is less than 7cm.
2. Bulk-related symptoms (e.g., pelvic pain, pressure or discomfort, urinary symptoms related to compression of the ureter or bladder) 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. Fibroid removal with power morcellation for the following indications in women without known or strongly suspected uterine cancer:
7. 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*
8. 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.
9. 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.

EXCLUSIONS:

D. The use of laparoscopic ultrasound-guided radiofrequency ablation (e.g.,Acessa) of uterine fibroids 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.

E. The use of transcervical ultrasound-guided radiofrequency ablation (e.g., Sonata) of uterine fibroids 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. 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. Member is pregnant at the time of the procedure
8. Member with an unusually short endometrial cavity (< 4.5 cm fundus-to external opening of cervix (os))

F. 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

G. MRI guided focused ultrasound (MRgFUS) (e.g., ExAblate) for the treatment of uterine fibroids

H. Myomectomy or hysterectomy using power morcellation for the removal of uterine fibroids for all other indications not listed in the inclusions above

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)

None identified	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None identified
First Coast Service Options, Inc.	None identified
Wellpoint Federal (formerly National Government Services, Inc.)	None identified
Noridian Healthcare Solutions	None identified
Novitas Solutions, Inc.	None identified
Palmetto GBA	None identified
WPS Insurance Corporation	None identified

III. BACKGROUND

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 nonsurgical 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. It has been studied as an alternative, potentially fertility-sparing modality for patients with uterine fibroids. However, at this time the available evidence on HIFU does not reliably demonstrate superior clinical or fertility outcomes. ACOG recognizes the limitations of this treatment: *"Limited, low-quality data suggest that magnetic resonance-guided focused ultrasound and high-intensity focused ultrasound are associated with a reduction in leiomyoma and uterine size. However, small randomized comparative trial data suggest that compared with UAE, magnetic resonance-guided focused ultrasound is associated with less improvement in symptoms and quality-of-life measures and a higher risk of reintervention. In a recent meta-analysis, the rate of reintervention at 60 months was 53.9%. Additional data are needed before recommendations can be made regarding the use of this treatment for uterine leiomyomas."* (ACOG, 2021) In a 2022 meta-analysis by Liu and colleagues, 10 studies involving 4,450 women were analyzed. Compared with the surgery group, the decrease in uterine fibroid severity score at 6- and 12-month follow-up was higher in the HIFU group (MD - 4.16, 95% CI - 7.39 to - 0.94, and MD - 2.44, 95% CI - 3.67 to - 1.20, $p < 0.05$). The increase in quality-of-life score at 6- and 12-month follow-up was higher in the HIFU group (MD 2.13, 95% CI 0.86 to 3.14, and MD 2.34, 95% CI 0.82 to 3.85, $p < 0.05$). The duration of hospital stay and the time to return to work was shorter in the HIFU group (MD - 3.41 days, 95% CI - 5.11 to - 1.70, and MD - 11.61 days, 95% CI - 19.73 to - 3.50, $p < 0.05$). The incidence of significant complications was lower in the HIFU group (RR 0.33, 95% CI 0.13 to 0.81, $p < 0.05$). The differences in the outcomes of adverse events, symptom recurrence, re-intervention, and pregnancy were not statistically significant ($p > 0.05$). Another systematic review by Yan and colleagues (2022) included 21 studies and revealed that HIFU had a higher re-intervention rate than uterine artery embolization (relative risk [RR] = 4.06, 95% confidence interval [CI]: 2.47-6.69) and offered no significant advantages in reducing the symptom severity score (SSS) (mean difference [MD] = 17.01, 95% CI: 10.25-23.77) and improving the health-related quality of life (HRQoL) score (MD= -18.32, 95% CI: -24.87 to -11.78) in the treatment of symptomatic uterine fibroids. This study did find that, compared with uterine artery embolization, HIFU *may* be associated with a higher pregnancy rate (RR = 17.44, 95% CI: 2.40-126.50) and may have a significant advantage in shortening pregnancy interval and preserving ovarian function. Moreover, upon comparing HIFU with traditional surgical treatments, the HIFU group showed significantly improved HRQoL score (MD = 2.25, 95% CI: 1.15-3.35), but the re-intervention rate (RR = 1.65, 95% CI: 0.59-4.57), pregnancy rate (RR = 1.01, 95% CI: 0.90-1.13), SSS and ovarian function did not significantly differ between the two groups.

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 uterinesparing 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 postpartum outcomes for women who desire to become pregnant is unknown.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American College of Obstetricians and Gynecologists (ACOG)	Management of Symptomatic Uterine Leiomyomas (2021)
American College of Obstetricians and Gynecologists (ACOG)	ACOG practice bulletin. Alternatives to hysterectomy in the management of leiomyomas (2008)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Decision date
Acessa ProVu System	K181124	9/28/2018
Acessa Guidance System	K132744	05/27/2014
Acessa Guidance Handpiece	K132184	04/28/2014
Exablate Model 2100V1, Exablate Prostate System, Exablate MRgFUS, Exablate 2100V1 Type 3.0	K231378	10/30/2023

Sonata® SonographyGuided Transcervical Fibroid Ablation System 2.1	K193516	05/04/2020
Sonata Transcervical Fibroid Ablation System 2.2	K211535	06/17/2021
Sonata Sonography-Guided Transcervical Fibroid Ablation System	K173703	08/15/2018

VI. CODING

See also *Priority Health Medical Policy No. 91636 - Category III Current Procedural Terminology (CPT®) Codes ("T" codes)*

ICD-10 Codes that may support medical necessity
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 Medically Necessary
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

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, 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, refer to the Priority Health Provider Manual.

To access Evicore guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

To access InterQual guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

To access TurningPoint guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

To access EviCore, InterQual, or TurningPoint guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the 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); 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. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, 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.

IX. REFERENCES

GENERAL UTERINE FIBROID MANAGEMENT

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TRANSCERVICAL ULTRASOUND-GUIDED RADIOFREQUENCY ABLATION (SONATA)

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SUMMARY OF CHANGES

Deletions:

- I.B.1 and 1.C.1– Removed requirement for fibroid to be palpable in the abdomen
- I.C.6 – Removed requirement for provider training and certification on Sonata

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Past committee 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, 8/26

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