

UTERINE FIBROID TREATMENT

Effective Date: November 17, 2016

Review Dates: 6/10, 6/11, 6/12, 6/13, 8/14, 8/15, 8/16,
8/17, 8/18, 11/18

Date Of Origin: June 9, 2010

Status: Current

Summary of Changes

Additions:

- Pg. 1, Section I. POLICY/CRITERIA: Added item 3. The use of sonography-guided transcervical radiofrequency ablation as a treatment for uterine fibroids (i.e. Sonata System) is considered investigational and not medically necessary.

I. POLICY/CRITERIA

1. The following procedures are covered when conservative medical management, typically hormonal therapies, has failed to control the symptoms attributable to uterine fibroids:
 - a. 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.
 - b. Myomectomy – the surgical removal of fibroids while leaving the uterus in place.
 - c. Hysterectomy - the surgical removal of the uterus. The ovaries may or may not be removed.
2. The use of laparoscopic or percutaneous ablation techniques in combination with imaging guidance as a treatment of uterine fibroids is considered investigational and not medically necessary, including but not limited to lasers, bipolar electrodes, interstitial thermotherapy, cryotherapy and radiofrequency ablation (i.e. HALT procedure / Acessa).
3. The use of sonography-guided transcervical radiofrequency ablation as a treatment for uterine fibroids (i.e. Sonata System) is considered investigational and not medically necessary.
4. MRI guided focused ultrasound (MRgFUS) (e.g. ExAblate) is considered to be experimental and investigational and not a covered benefit.
5. Fibroid removal with power morcellation is considered medically necessary for the following indications in women without known or strongly suspected uterine cancer:

- a. 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*
- b. 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.

II. MEDICAL NECESSITY REVIEW

Required Not Required Not Applicable

III. 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); 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). Ultrasound waves, directed at the fibroids through the skin with the help of magnetic resonance imaging, are used to destroy fibroids.

V. CODING INFORMATION

ICD-10 Codes that may apply (*for dates of service on or after October 1, 2015*):

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

- D26.0 Other benign neoplasm of cervix uteri
- D26.1 Other benign neoplasm of corpus uteri
- D26.7 Other benign neoplasm of other parts of uterus
- D26.9 Other benign neoplasm 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
- 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
- 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

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
- 0404T Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency

- 58674 Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency

VI. REFERENCES

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