



Missouri Care

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Children's Medical Services Health Plan (CMS Health Plan)

WellCare (Alabama, Arizona, Arkansas, California, Connecticut, Florida, Georgia, Illinois, Indiana, Louisiana, Maine, Michigan, Mississippi, Missouri, New Hampshire, New Jersey, New York, North Carolina, Ohio, South Carolina, Tennessee, Texas, Washington)

WellCare Prescription Insurance

WellCare TexanPlus (Houston & Dallas markets)

Fibroid Treatment

Policy Number: HS-213

Original Effective Date: 6/2/2016

Revised Date(s): 5/4/2017; 4/5/2018, 4/4/2019

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any. All links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change prior to the annual review date. Lines of business (LOB) are subject to change without notice; current LOBs can be found at www.wellcare.com. All guidelines can be found at this site as well by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

Uterine fibroids (or leiomyomas) are benign soft tissue neoplasms that arise from smooth muscle. These lesions can develop wherever smooth muscle is present, but malignant transformation probably does not occur. The most common feature in patients with multiple piloleiomyomas (cutaneous leiomyomas) is pain, which can be spontaneous or induced by cold or tactile (e.g., pressure) stimuli. The pain or tenderness also may be secondary to pressure on nerve fibers within the tumor; however, some authors believe it may be solely due to contraction of

muscle fibers. Symptoms are also reported to occur with menses or pregnancy. Many solitary piloleiomyomas are similarly symptomatic. However, genital leiomyomas are usually asymptomatic solitary lesions arising from the dartoic, vulvar, or mammillary muscles in the genital region or on the nipple. Features of individual piloleiomyomas include the following:¹

- Smooth, firm papules or nodules
- Usually smaller than 2 cm in diameter
- Reddish brown in color
- Usually tender to palpation
- Usually found on a lower extremity
- Fixed in the skin but can be easily moved over the deeper subcutaneous tissues

Multiple piloleiomyomas can occur on the face, trunk, or extremities. Various distribution patterns are reported, including bilaterally symmetric, grouped, dermatomal, and linear patterns. Features of angioleiomyomas (vascular leiomyomas) include the following:¹

- Most commonly present as solitary skin-colored nodules
- Usually well-defined, fairly deep dermal nodules that are smaller than 4 cm
- Often, pain to palpation
- Occur predominantly on the lower extremities, less commonly on the head or trunk, and rarely on the hands or in the mouth.

Leiomyomas of the vulva or scrotum may be larger than those already described above. Leiomyomas of the nipple and piloleiomyomas are generally similar in size.¹

Testing, Imaging Studies, and Procedures

Laboratory testing is generally not necessary for evaluation of leiomyomas unless there is abnormal vaginal bleeding or to rule out other conditions. The measurement of hemoglobin and/or hematocrit levels might be considered in patients with multiple leiomyomas, because erythrocytosis is reported in rare cases. Imaging studies are not routinely performed for leiomyomas; however, angioleiomyomas do have characteristic findings on ultrasonographic (including color Doppler) and magnetic resonance images. Uterine leiomyomas may be assessed by Doppler ultrasonography assessment before uterine artery embolization. Tissue examination is necessary to establish the diagnosis. Therefore, a partial or excisional biopsy is indicated.¹

Medical Literature Review

The incidence of these estrogen-dependent tumors increases with age until menopause. In the sixth decade of life, the prevalence of fibroids approaches 70% in Caucasian women and 80% in black women. Fibroids are categorized as intramural (within the uterine wall), submucosal (projecting into the cavity of the uterus), or subserosal (projecting into the abdominal cavity). They can produce pain, pressure, frequent and heavy bleeding, infertility, urinary frequency, dyspareunia (pain during intercourse), and miscarriage. The annual cost of medical care is more than 3 times higher for women with fibroids than for those without these benign tumors. The annual cost for care of women with fibroids in the United States is estimated at \$2 billion, and this figure does not include time lost from work and other indirect costs. In the United States, fibroids are the most common indication for hysterectomy.^{2,3,4,5,6,7,8}

Treatments for symptomatic fibroids include medical management, hysterectomy, myomectomy (removal of the fibroids while leaving the uterus in situ), radiofrequency ablation (RFA), uterine artery embolization (UAE), laser ablation, cryoablation, and image-guided thermal ablation using ultrasonography (US) or magnetic resonance imaging (MRI). Medical treatments include hormonal manipulation, estrogen receptor modulators, antifibrinolytic agents, and gonadotropin-releasing hormone (GnRH) agonists. GnRH agonists can produce dramatic shrinkage of fibroids, but are not appropriate for chronic use, and the tumors quickly regrow when the drug is withdrawn. Most other 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.^{2,3,4,5,6,7,8}

Therapies

Thermal therapies for fibroids, often performed under imaging guidance, ablate fibroids by heating them rapidly, creating intracellular ionic agitation. This creates frictional heat and areas of necrosis (cellular death) within the fibroid, which reduces tumor and uterine volume, and relieves symptoms. Volumetric, image-guided ablation spares surrounding tissue and minimizes the number of required ablations, thus reducing the possibility of adhesions, uterine injury, and bleeding. Use of transvaginal US to identify fibroids is of limited value when the uterus is bulky or retroverted, and abdominal US is difficult in obese women.^{2,5,3,8,9}

The Acessa System (Halt Medical Inc.) is a minimally invasive, US-guided system for performing laparoscopic radiofrequency volumetric thermal ablation (RFVTA) of fibroids in the outpatient setting. The system includes a dual-function generator, a disposable handpiece equipped with a 7-electrode array, disposable dispersive electrode pads, a foot pedal and accompanying power cord, and connecting cables, and generates up to 200 Watts of power. Side-by-side monitors display the laparoscopic and ultrasonographic image during the procedure. Two standard laparoscopic ports are used: a 5-millimeter (mm) infraumbilical port for the laparoscope and a 10-mm suprapubic port for the ultrasonic transducer. In addition, the handpiece is inserted through a small skin incision under laparoscopic guidance. After induction of general anesthesia, the procedure begins with a survey of the uterus. Laparoscopic US offers the ability to locate fibroids that are not detectable by external US methods. The uterus is mapped and the surgeon confirms the location of the fibroids. The proximity of the US transducer to the tumor allows generation of high-resolution images and permits the surgeon to directly examine the fibroid from any direction or angle.^{2,9,4,6,7}

Once a fibroid is selected for treatment, the handpiece is inserted 1 centimeter (cm) into the tumor and the electrode array is deployed. The physician controls the generator using buttons on the handpiece control. Ablation is initiated and terminated by depressing the foot pedal (Halt Medical Inc., 2012). Unlike early thermal ablation methods that did not allow the surgeon to assess the extent of ablation, real-time feedback on the anatomical location of the probe and the temperature of the tissue aid in targeting the area of tissue and avoiding damage to surrounding normal structures (Shen et al., 2009; Halt Medical Inc., 2012). The voltage, current, and temperature within the target tissue are continuously monitored by thermocouples in the electrode, and the generator adjusts the power delivered to keep the temperature constant throughout the ablation. Multiple fibroids may be treated through a single uterine puncture. In addition to radiofrequency energy for ablation, the generator also performs traditional electrocautery for control of bleeding. Once the ablation is completed, the surgeon switches the generator to coagulation mode to seal the tract during withdrawal of the handpiece.^{2,5,9}

Uterine fibroid ablation with the Acessa system is performed by a physician, typically, a board-certified obstetrician-gynecologist with basic laparoscopic and sonographic skills who has received training in the use of the device. The target population is women with symptomatic fibroids who desire uterine sparing and have completed childbearing. The procedure requires up to 2 hours, depending on the number of fibroids. No suturing or uterine incisions are required. Most patients need only nonsteroidal anti-inflammatory drugs (NSAIDs) for postoperative pain relief and can return to normal activities within 4 to 5 days.^{2,9}

Food and Drug Administration (FDA)

Under the 510(k) approval process, the FDA cleared the following Class II ablation systems and accessories (Halt Medical Inc.) as unipolar endoscopic coagulator-cutter and accessories (product code HFG) and as substantially equivalent to legally marketed predicate devices:²

- The Halt 2000GI Electrosurgical Radiofrequency Ablation System (K094009) cleared on June 14, 2010. The Ablation System is indicated for use in percutaneous, laparoscopic, and intraoperative coagulation and ablation of soft tissue. Its components are: Radiofrequency (RF) Generator, Disposable RF Probe, RF Probe Extension Cable, Dispersive Electrode Pads, Dispersive Electrode Pad Set Extension Cable, Power Cord, and Foot Pedal.²

- The Acesa System (K121858) cleared on November 5, 2012. The Acesa System is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. Its components are: Generator, Handpiece, Handpiece Cable, Pads and Cable, Power Cord, and Foot Pedal. The technological characteristics of the Acesa System are equivalent to the Halt 2000GI System. Although the intended therapeutic effects of the 2 devices are the same, the Acesa System includes the specific indication of treatment of symptomatic uterine fibroids.²
- The Acesa Guidance Handpiece (K132184) cleared on April 28, 2014 and is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance.²

NOTE: The Acesa Guidance Handpiece is the same product as the Acesa System with the exception of the addition of the embedded sensor so that the device may also be used, if desired, with electromagnetic tracking technologies that can draw a virtual representation of the device.

- The Acesa Guidance System (K132744) cleared on May 27, 2014 and is indicated for enhancing the ultrasonic image of the Acesa 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 Acesa System procedure. Its components are: Guidance Controller, Guidance Ultrasound, Guidance Field Generator, Guidance Handpiece Cable, and Power Cord. Search the FDA 510(k) Premarket Notification (PMN) database by HFG in the product code field for additional ablation systems and accessories.²

POSITION STATEMENT

Applicable To:

- Medicaid (excluding KY)
- Medicare (excluding KY)
- Children's Medical Services Health Plan (CHIP)

Exclusions

Exclusions and contraindications for the Acesa System include the following:²

- Members who are not candidates for laparoscopic surgery due to known or suspected intra-abdominal adhesions; **OR**
- Members who have bleeding disorders, uteri adherent to pelvic tissue or viscera, or those with non-uterine pelvic masses; **OR**
- Members with metal implants near the ablation site or along the return path to the grounding pads.

Radiofrequency ablation **is considered experimental and investigational** due to a lack of established efficacy for the treatment of symptomatic uterine fibroids. Further, EA is contraindicated in women with the following conditions or characteristics:^{9,13}

- Pregnancy
- Known or suspected endometrial hyperplasia or cancer
- Desire to preserve fertility
- Active pelvic infection
- Intrauterine device (IUD) in place
- Previous transmyometrial uterine surgery
- Postmenopausal
- Congenital uterine anomalies (e.g., bicornuate uterus)
- Uterine cavity length greater than 10 to 12 cm
- Severe myometrial thinning

The following treatments for uterine fibroids **are considered experimental and investigational** due to a lack of established safety and efficacy:

- Acupuncture
- Cryomyolysis
- Laparoscopic uterine artery occlusion
- Cryotherapy, interstitial thermotherapy, lasers, and ultrasound (focused ultrasound) ablation, with or without MRI guidance.

Coverage

Radiofrequency ablation **is considered medically necessary** as an alternative to hysterectomy or myomectomy for the treatment of uterine fibroids in patients with persistent symptoms directly attributed to uterine fibroids such as excessive menstrual bleeding (menorrhagia); bulk-related pelvic pain, pressure, and/or discomfort; urinary symptoms referable to compression of the ureter or bladder; and/or dyspareunia.²

CODING

Covered CPT®* Codes

- 58674** Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency
- 0404T** Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency

Covered ICD-10 Diagnosis Codes

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

For excessive menstrual bleeding (menorrhagia)

- N92.0** Excessive and frequent menstruation with regular cycle
- N92.1** Excessive and frequent menstruation with irregular cycle
- N92.2** Pubertal (menses retained)
- N92.4** Pre-climacteric or climacteric; pre-menopausal period
- N95.0** Postmenopausal bleeding

For bulk-related pelvic pain, pressure, and/or discomfort

- R10.2** Pelvic and perineal pain

For urinary symptoms referable to compression of the ureter or bladder

- N13.5** Crossing vessel and stricture of ureter without hydronephrosis

For dyspareunia

- F52.6** Nonorganic or psychogenic
- N94.10** Unspecified dyspareunia
- N94.11** Superficial (introital) dyspareunia
- N94.12** Deep dyspareunia
- N94.19** Other specified dyspareunia

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal/ state laws.

REFERENCES

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MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
4/4/2019, 4/5/2018	<ul style="list-style-type: none"> • Approved by MPC. No changes.
5/4/2017	<ul style="list-style-type: none"> • Approved by MPC. Additional exclusions from retired guideline, Ablation of Uterine Fibroids(E/I) HS-287.
6/2/2016	<ul style="list-style-type: none"> • Approved by MPC. New.