Medica Coverage Policy

Policy Name:	**Radiofrequency Ablation of Uterine Fibroids**
Effective Date:	**09/16/2024**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

Laparoscopic radiofrequency ablation (RFA) for the treatment of uterine fibroids **IS COVERED**.

All other forms of RFA for treating uterine fibroids (e.g. transvaginal, transcervical) are considered investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Note: See also related Position Statement, *High Intensity Focused Ultrasound (HIFU) and Magnetic Resonance Guided Focused Ultrasound (MRgFUS)*

Note: See also related Clinical Guideline*, Management of Benign Uterine Conditions.*

Description

Standard therapies for management of symptomatic uterine fibroids (aka, leiomyoma, myoma) include medical management, uterine artery embolization (UAE), myomectomy, and hysterectomy. Surgery, including hysterectomy and myomectomy, is considered the gold standard for symptom resolution. However, there is the need to recover from surgery, and in the case of a hysterectomy, the uterus is not preserved. UAE is associated with poor pregnancy outcomes and is not advised in patients who desire to become pregnant. The purported intent of RFA for treatment of uterine fibroids is to provide a treatment option that is an alternative to or an improvement on existing therapies.

RFA was approved in the United States in 2012 as a procedure for improving painful symptoms caused by fibroids. The benefits of RFA are purported to include relief from fibroid symptoms within three to six months, protection of healthy surrounding tissue, avoidance of premature menopause, and an early return to activities of daily living. The procedure is indicated when fibroids are not excessively large, the uterus is located below the naval, and there is no history of past complex abdominal surgeries. RFA reduces the size of fibroids but does not eliminate them. Fibroids can regrow, and new fibroids may develop after the procedure. There currently remains limited long-term data regarding pregnancy and pregnancy outcomes following RFA therapy.

During laparoscopic or transcervical RFA, ultrasound guidance is used to better define the area of fibroid tissue to

be treated. After treatment area is defined, several small RF needles are introduced into the fibroid(s) using either a laparoscopic or transcerival approach, and are heated to 105 degrees Celsius in order to induce ablation of the fibroid tissue, while sparing surrounding healthy tissue. The intent is to disrupt the blood flow to the treated fibroid, resulting in shrinking and tissue reabsorption. RFA is typically an outpatient procedure, taking approximately 1.5 to 7 minutes depending on the size of the area to be treated.

FDA Approval
The Sonata System (Gynesonics, Inc), which uses a transcervical approach, was initially granted FDA 510(k) approval (K173703) in August 2018. Subsequently, the Sonata System 2.2 received FDA 510(k) approval (K211535) in May 2021. The FDA labeled indication states: "The Sonata Sonography-Guided 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."

The Acessa System (Acessa), which uses a laparoscopic approach, was initially granted FDA 510(k) approval in November 2012, and the Acessa ProVu System received FDA 510(k) approval in September 2018. The system is approved for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. The system includes the option of electromagnetic guidance for enhancing the ultrasonic image and for predicting its future path.

Prior Authorization

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

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

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