02-56000-30

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Subject: Laparoscopic and Percutaneous Techniques for the Treatment of Uterine Fibroids

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DESCRIPTION:

Various minimally invasive treatments for uterine fibroids (also called leiomyomas, fibromyomas, fibromas, myofibromas, and myomas) have been proposed as alternatives to surgery. Among these approaches are laparoscopic and percutaneous techniques to induce myolysis, which includes radiofrequency ablation (RFA), lasers, bipolar needles and electrodes, cryomyolysis, and magnetic resonance imaging-guided laser ablation.

Several radiofrequency ablation systems have been approved by the U.S. Food and Drug Administration (FDA) (e.g., Acessa™, Sonata®). The Acessa System is intended for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. 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.

Summary and Analysis of Evidence: Peer-reviewed evidence from several clinical studies, randomized controlled trials, prospectve an observational studies suggests that laparoscopic anr radiofrequency ablation techniques works for ablation of uterine fibroids. A randomized controlled trial by Yu et al 2022 to determine the efficacy, safety, and healthcare resource use of laparoscopic radiofrequency ablation (LAP-RFA) compared with myomectomy in patients with symptomatic uterine leiomyomas (ULs). The main outcome measures of this study were part of the secondary outcomes of the original TRUST trial. The primary outcome of this study was the reduction of UL symptoms and the improvement in patient-reported outcomes scores over time. Secondary outcomes included post-procedure hospitalization, length of stay, complications, reinterventions, and recovery time. There was a significant improvement in UL symptoms at 3 and 12 months after the procedure within each treatment group, and these improvements were similar between treatment groups. There was a significant reduction in UL

symptoms per month between baseline and 12-months after the procedure for both LAP-RFA and myomectomy of 72% and 85%, respectively. A significant improvement was seen in all patient-reported outcomes scores over time for both groups. At 3 and 12 months after the procedure, the percentages of patients who were hospitalized in the LAP-RFA group were 74% and 49% lower than those of patients in the laparoscopic myomectomy group, respectively, with the 3-month difference being statistically significant. The length of hospital stay was significantly shorter in the LAP-RFA group compared with the myomectomy group (8.0 ± 5.7 hours vs 18.8 ± 14.6 hours; $p < .05$). Doctors recommended taking significantly less time off before returning to work for the patients in the LAP-RFA group compared with those in the myomectomy group (10.3 ± 5.1 days vs 14.5 ± 5.4 days; $p < .05$). The total number of days until back to normal activity was significantly lower in the LAP-RFA group compared with the myomectomy group (16.3 ± 15.2 days vs 26.5 ± 15.9 days; $p < .05$). The results from this 12-month follow-up study suggest that LAP-RFA is a safe, effective, uterine-sparing alternative to laparoscopic myomectomy in the treatment of ULs. These data points build on previously published studies showing that LAP-RFA has lower healthcare resource use overall, including lower post-procedure hospitalization rate and shorter length of stay. In clinical practice, LAP-RFA is a promising treatment approach to ULs for women.

Lukes et al. (2020) reports on 3-year clinical outcomes of the Sonography Guided Transcervical Ablation of Uterine Fibroids (SONATA) pivotal trial of transcervical fibroid ablation (TFA) in women with symptomatic uterine myomata. The SONATA, prospective, controlled, multicenter interventional trial, enrolled 147 premenopausal women with symptomatic uterine fibroids who underwent uterus-preserving, sonography-guided TFA with the SonataSystem (Gynesonics, Inc., Redwood City, CA, USA). Clinical outcomes were assessed over 3 years and included surgical reinterventions, Symptom Severity Score (SSS), and Health-Related Quality of Life (HRQoL) subscales of the Uterine Fibroid Symptom and Quality-of-Life Questionnaire, EuroQol 5-Dimension (EQ-5D) questionnaire, Overall Treatment Effect, treatment satisfaction, physical activity, work impairment, pregnancy outcomes, and adverse events. The 3-year rates of surgical reintervention for heavy menstrual bleeding calculated by the binomial and Kaplan–Meier methods were 9.2% and 8.2%, respectively. Compared to baseline, mean SSS decreased from 55–19 to 22–21, HRQoL increased from 40–21 to 83–23, and EQ-5D increased from 0.72–0.21 to 0.88–0.16 (all $p<0.001$). Treatment benefit on the SSS, HRQoL, and EQ-5Q exceeded the minimal clinically important difference at every follow-up visit over 3 years. At 3 years, 94% of the subjects reported treatment satisfaction, 88% reported reduced fibroid symptoms, work absenteeism due to fibroid symptoms decreased from 2.9% to 1.4%, and impairment due to fibroids decreased from 51% to 12% for work, and 58% to 14% for physical activity (all $p<0.001$). No late complications occurred. The authors concluded that women treated with sonography-guided TFA in the SONATA pivotal trial experienced significant and durable reduction of fibroid-related symptoms, with low surgical reintervention rates over 3 years of follow-up.

POSITION STATEMENT:

Laparoscopic or transcervical radiofrequency ablation (RFA) using an FDA approved device (e.g., Acessa™, Sonata®) as a treatment of symptomatic uterine fibroids **meets the definition of medical necessity** in members 18 years and older when ALL of the following conditions are met:

- Evidence of uterine fibroids via ultrasound that are less than 10 cm in diameter for laparoscopic RFA with Acessa or 7 cm for transcervical RFA with Sonata; **AND**

- Member desires a uterine-sparing treatment approach or is ineligible for hysterectomy or other uterine-sparing alternatives to RFA (e.g., laparoscopic myomectomy, uterine artery embolization [UAE]); **AND**
- Member has experienced at least 1 of the following symptoms that are a direct result of the uterine fibroid(s):
    - Menorrhagia or other abnormal uterine bleeding that interferes with daily activities or causes anemia;
    - Pelvic pain or pressure;
    - Urinary symptoms related to bulk compression of the bladder (e.g., urinary frequency, urgency);
    - Gastrointestinal symptoms related to bulk compression of the bowel (e.g., constipation, bloating);
    - Dyspareunia (painful or difficult sexual relations).

All other techniques of myolysis, including but not limited to (e.g., Nd: Yag laser, bipolar needles and electrodes, supercooled cryoprobes, cryomyolysis, magnetic resonance imaging-guided laser ablation) as a treatment of uterine fibroids are considered **experimental or investigational**. The evidence is insufficient to determine the effects of the technology on health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

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

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of review.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

Transcatheter Uterine Artery Embolization and Occlusion of Uterine Arteries for the Treatment of Uterine Fibroids, 02-56000-26

Magnetic Guided High Intensity Ultrasound , 02-56000-27

OTHER:

Other names used to report laparoscopic and percutaneous techniques for the treatment of uterine fibroids:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Crymomyolysis
Laparoscopic ultrasound-guided radiofrequency ablation
Laparoscopic ultrasound-guided radiofrequency volumetric thermal ablation (RFVTA)
Laparoscopic uterine artery occlusion
Laparoscopic myolysis
Myolysis
Percutaneous myolyisis
Radiofrequency ablation
Transcervical ablation
Transcervical fibrod ablation (TFA)
Transcervical radiofrequency (RF) ablation
Ultrasound-guided transcervical ablation

In November 2014, the U.S. Food and Drug Administration (FDA) published a safety communication on laparoscopic power morcellators in hysterectomy and myomectomy. FDA recommends that manufacturers of laparoscopic power morcellators include in their product labeling specific safety statements in the form of a boxed warning and contraindications.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 06/26/25.

GUIDELINE UPDATE INFORMATION:

11/15/14	New Medical Coverage Guideline.
11/01/15	Revision: ICD-9 Codes deleted.
12/15/15	Review; added “including but not limited to (e.g., Nd: YAG lasers, bipolar electrodes, supercooled cryoprobes, radiofrequency ablation)” to position statement. Added FDA safety communication statement on laparoscopic power morcellators used for myomectomy and hysterectomy. Updated references.
01/01/16	Annual HCPCS code update. Added 0404T.
12/15/16	Annual review; no change to position statement. Updated references.
11/15/17	Review; no change to position statement, Updated program exception and references.
11/15/18	Review; added “of myolysis’ to position statement. Updated references.

10/15/19	Review; no change in position statement.
01/20/21	Code update. Deleted 0336T. Added 58674.
04/15/21	Annual review; added medical necessity criteria for radiofrequency ablation for uterine fibroids. Updated references.
07/15/23	Review; revised position statement. Updated references.
01/01/24	Annual CPT/HCPCS coding update. Added 58580. Deleted 0404T.
07/15/24	Review; no change in position statement. Updated references.
07/15/25	Review; no change in position statement. Updated references.