

02-56000-30

Original Effective Date: 11/15/14

Reviewed: 06/27/24

Revised: 07/15/24

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

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

[Position Statement](#)

[Billing/Coding](#)

[Reimbursement](#)

[Program Exceptions](#)

[Definitions](#)

[Related Guidelines](#)

[Other](#)

[References](#)

[Updates](#)

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, prospective and observational studies suggests that laparoscopic and radiofrequency ablation techniques work 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.

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.

Cryomyolysis

Laparoscopic ultrasound-guided radiofrequency ablation

Laparoscopic ultrasound-guided radiofrequency volumetric thermal ablation (RFVTA)

Laparoscopic uterine artery occlusion

Laparoscopic myolysis

Myolysis

Percutaneous myolysis

Radiofrequency ablation

Transcervical ablation

Transcervical fibroid 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.

REFERENCES:

1. American College of Obstetricians and Gynecologists (ACOG). Alternatives to hysterectomy in the management of leiomyomas. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2008 Aug. 14 p. (ACOG practice bulletin; no. 96).
2. Bends R, Toub DB, Römer T. Normal spontaneous vaginal delivery after transcervical radiofrequency ablation of uterine fibroids: a case report. *Int J Womens Health* 2018 Jul 16; 10:367-369.
3. Blue Cross Blue Shield Association Evidence Positioning System®. 4.01.19 Laparoscopic, Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis, 03/24.
4. Berman JM, Guido RS, Garza Leal JG et al. Three-year outcome of the Halt trial: a prospective analysis of radiofrequency volumetric thermal ablation of myomas. *Journal of Minimally Invasive Gynecology* 2014; 21(5): 767-74.
5. Bongers M, Brölmann H, Gupta J, et al. Transcervical, intrauterine ultrasound-guided radiofrequency ablation of uterine fibroids with the VizAblate® System: three- and six-month endpoint results from the FAST-EU study. *Gynecol Surg.* 2015;12(1):61-70.

6. Bongers M, Gupta J, Garza-Leal JG et al. The INTEGRITY trial: preservation of uterine-wall integrity 12 months after transcervical fibroid ablation with the Sonata System, *J Gynecol Surg* 2019; 35(5):299-303.
7. Bongers M, Quinn SD, Mueller MD et al. Evaluation of uterine patency following transcervical uterine fibroid ablation with the Sonata system (the OPEN clinical trial). *Eur J Obstet Gynecol Reprod Biol.* 2019 Nov; 242:122-125.
8. Bradley LD, Pasic RP, Miller LE. Clinical performance of radiofrequency ablation for treatment of uterine fibroids: systematic review and meta-analysis of prospective studies. *J Laparoendosc Adv Surg Tech A.* 2019 Dec;29(12):1507-1517. Braun KM, Sheridan M, Latif EZ et al. Surgeons' early experience with the Acessa™ procedure: gaining proficiency with new technology. *International Journal of Women's Health* 2016. Nov; 8:669-675.
9. Brölmann H, Bongers M, Garza-Leal JG et al. The FAST-EU trial: 12-month clinical outcomes of women after intrauterine sonography-guided transcervical radiofrequency ablation of uterine fibroids. *Gynecol Surg.* 2016; 13:27-35.
10. Brooks E, Mihalov L, Delvadia D et al. The INSPIRE comparative cost study:12-month health economic and clinical outcomes associated with hysterectomy, myomectomy, and treatment with the Sonata system. *Clinicoecon Outcomes Res* 2020 Jan 8; 12:1-11.
11. Brooks EA, Singer AM, Delvadia DR, et al. The CHOICES study: facility level comparative cost, resource utilization, and outcomes analysis of myomectomy compared to transcervical fibroid ablation. *Clinicoecon Outcomes Res.* 2020 Jun 12;12: 299-306.
12. Brucker SY, Hahn M, Kraemer D, et al. Laparoscopic radiofrequency volumetric thermal ablation of fibroids versus laparoscopic myomectomy. *International Journal of Gynecology and Obstetrics* 2014; 125(3): 261-265.
13. Christoffel L, Bends R, Toub D, et al. Pregnancy Outcomes After Transcervical Radiofrequency Ablation of Uterine Fibroids with the Sonata System. *J Gynecol Surg.* Jun 01 2022; 38(3): 207-213.
14. Christoffel L, Römer T, Schiermeier S. Transcervical radiofrequency ablation of uterine fibroids global registry (SAGE): study protocol and preliminary results. *Med Devices (Auckl).* 2021 Mar 3;14:77-84.
15. Chudnoff SG, Berman JM, Levine DJ et al. Outpatient procedure for the treatment and relief of symptomatic uterine myomas. *Obstetrics and Gynecology* 2013; 121(5): 1075-82.
16. Chudnoff S, Guido R, Roy K et al. Ultrasound-guided transcervical ablation of uterine leiomyomas. *Obstet Gynecol* 2019; 133:13-22.
17. Galen DI. Electromagnetic image guidance in gynecology: prospective study of a new laparoscopic imaging and targeting technique for the treatment of symptomatic uterine fibroids. *Biomedical Engineering Online* 2015; 40:90.
18. Galen DI, Pemueler RR, Leal JG et al. Laparoscopic radiofrequency fibroid ablation: Phase II and Phase III Results. *Journal of the Society of Laparoendoscopic Surgeons* 2014; 18(2): 182-190.
19. Garza-Leal JG. Long-term clinical outcomes of transcervical radiofrequency ablation of uterine fibroids: the VITALITY study. *J Gynecol Surg* 2019; 35:19-23.
20. Garza-Leal J.G., Toub, D., León, I.H. et al. Pregnancy after transcervical radiofrequency ablation guided by intrauterine sonography: case report. *Gynecol Surg* 2014; 11: 145-149.
21. Garza-Leal J.G., Toub, D., León, I.H. et al. Transcervical, intrauterine ultrasound-guided radiofrequency ablation of uterine fibroids with the VizAblate System: safety, tolerability, and ablation results in a closed abdomen setting. *Gynecol Surg* 2011; 327–334.

22. Grube M, Neis F, Brucker SY, et al. Uterine fibroids-current trends and strategies. *Surg Technol Int* 2019 May 15; 34:257-263 [Abstract].
23. Guido RS, Macer JA, Abbott K et al. Radiofrequency volumetric thermal ablation of fibroids: a prospective, clinical analysis of two years' outcome from the Halt trial. *Health and Quality Life Outcomes* 2013; 11:139
24. Guido R, Stuparich M. Radiofrequency ablation new paradigm for treatment of fibroids. *Contemporary OBGYN.net* Oct 2016.
25. Hahn M, Brucker S, Kraemer D et al. Radiofrequency volumetric thermal ablation of fibroids and laparoscopic myomectomy: long-term follow-up from a randomized trial. *Geburtshilfe Frauenheilkd* 2015; 75(5):442-449.
26. Havryliuk Y, Setton R, Carlow JJ et al. Symptomatic Fibroid Management: Systematic Review of the Literature. *Journal of the Society of Laparoendoscopic Surgeons* 2017. Jul-Sep; 21 (3): e2017.00041.
27. Hudgens J, Johns DA, Lukes AS et al. 12-month outcomes of the US patient cohort in the SONATA pivotal IDE trial of transcervical ablation of uterine fibroids. *Int J Women's Health* 2019 Jul 5; 11:387-394.
28. Huirne J, Brooks E. Improvement in health utility after transcervical radiofrequency ablation of uterine fibroids with the sonata system: Health utility after radiofrequency ablation. *Eur J Obstet Gynecol Reprod Biol.* 2018 May; 224:175-180.
29. Ierardi AM, Carnevale A, Pellegrino F et al. Uterine myomas: extravascular treatment. *Semin Ultrasound CT MR.* 2021 Feb;42(1):56-74.
30. Jacoby VL, Parvataneni R, Oberman E et al. Laparoscopic radiofrequency ablation of uterine leiomyomas: clinical outcomes during early adoption into surgical practice. *J Minim Invasive Gynecol.* 2020 May-Jun Jun; 27(4):915-925.
31. Jones S, O'Donovan P, Toub D. Radiofrequency ablation for treatment of symptomatic uterine fibroids. *Obstet Gynecol Int.* 2012; 2012:194839.
32. Keltz J, Levie M, Chudnoff S. Pregnancy Outcomes After Direct Uterine Myoma Thermal Ablation: Review of the Literature. *J Minim Invasive Gynecol.* 2017 May-Jun;24(4):538-545.
33. Kramer B, Hahn M, Taran FA, et al. Interim analysis of a randomized controlled trial comparing laparoscopic radiofrequency volumetric thermal ablation of uterine fibroids with laparoscopic myomectomy. *International Journal of Gynecology and Obstetrics* 2016;133(2):206-211.
34. Lee BB, Yu SP. Radiofrequency Ablation of Uterine Fibroids: a Review. *Curr Obstet Gynecol Rep.* 2016;5(4):318-324.
35. Lin L, Ma H, Wang J et al. Quality of life, adverse events, and reintervention outcomes after laparoscopic radiofrequency ablation for symptomatic uterine fibroids: a meta-analysis. *J Minim Invasive Gynecol.* 2019 Mar-Apr;26(3):409-416.
36. Lukes A, Green MA. Three-year results of the SONATA pivotal trial of transcervical fibroid ablation for symptomatic uterine myomata. *J Gynecol Surg* 2020.
37. Miller CE, Osman KM. Transcervical radiofrequency ablation of symptomatic uterine fibroids: 2-year results of the SONATA pivotal trial. *J Gynecol Surg* 2019; 35:345-349.
38. National Institute for Health and Care Excellence (NICE). Interventional procedures guidance: Transcervical ultrasound-guided radiofrequency ablation for symptomatic uterine fibroids [IPG689]. March 31, 2021.
39. Parker WH. Uterine fibroids (leiomyomas): Laparoscopic myomectomy and other laparoscopic treatments. In: *UpToDate, Post TW (Ed), UpToDate, Waltham, MA.* (Accessed on March 30, 2023.)

40. Polin M, Hur HC. Radiofrequency Ablation of Uterine Myomas and Pregnancy Outcomes: An Updated Review of the Literature. J Minim Invasive Gynecol. Jun 2022; 29(6): 709-715.
41. Pschadka G, Engelhardt M, Niehoff C, Toub D. Term delivery in an infertile patient after transcervical radiofrequency Fibroid ablation and assisted reproductive technology J Gynecol Surg. 2019 Aug 1;35(4):253-255.
42. Shifrin G, Engelhardt M, Gee P et al. Transcervical fibroid ablation with the Sonata® system for treatment of submucous and large uterine fibroids. Int J Gynaecol Obstet. 2021 Feb 5.
43. Taheri M, Galo L, Potts C et al. Nonresective treatments for uterine fibroids: a systematic review of uterine and fibroid volume reductions. Int J Hyperthermia. 2019;36(1):295-301.
44. Thompson MJ, Carr BR. Intramural myomas: to treat or not to treat. International Journal of Women's Health 2016; 8: 145-149.
45. Toub DB. A new paradigm for uterine fibroid treatment: transcervical, intrauterine sonography-guided radiofrequency ablation of uterine fibroids with the Sonata System. Curr Obstet Gynecol Rep. 2017;6(1):67-73.
46. Vilos GA, Allaire C, Laberge PY et al. The management of uterine leiomyomas. Journal of Obstetrics and Gynaecology Canada 2015; 37(2): 157-178.
47. Yin G, Chen M, Yang S et al. Treatment of uterine myomas by radiofrequency thermal ablation: a 10-year retrospective cohort study. Reproductive Sciences 2015; 22 (5): 609-614.
48. Yu S, Bhagavath B, Shobeiri SA, et al. Clinical and Patient Reported Outcomes of Pre- and Postsurgical Treatment of Symptomatic Uterine Leiomyomas: A 12-Month Follow-up Review of TRUST, a Surgical Randomized Clinical Trial Comparing Laparoscopic Radiofrequency Ablation and Myomectomy. J Minim Invasive Gynecol. 2022 Jun;29(6):726-737. [Abstract]

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 06/27/24.

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.