Radiofrequency Ablation of Uterine Fibroids Clinical Coverage Criteria

Description

Radiofrequency ablation of uterine fibroids can be accomplished using laparoscopic, transvaginal and transcervical approaches. This policy applies to laparoscopic radiofrequency ablation using the Acessa System (Halt Medical, Inc., now Acessa Health), and transcervical radiofrequency ablation using the Sonata® Transcervical Fibroid Ablation System (Gynesonics, Inc., Redwood City, CA).

Policy

This Policy applies to the following Fallon Health products:

☒ Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
☒ MassHealth ACO
☒ NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
☒ NaviCare SCO (MassHealth-only)
☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
☒ Community Care (Commercial/Exchange)

Radiofrequency ablation of uterine fibroids is covered for MassHealth members only, and effective for dates of service on or after 06/01/2025 does not require prior authorization.

Fallon Health Clinical Coverage Criteria

Fallon Health Clinical Coverage Criteria apply to Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central) and Community Care members.

Fallon Health considers radiofrequency ablation as a treatment for symptomatic uterine fibroids experimental/investigational and not medically necessary.

Medicare Variation

None.

Medicare statutes and regulations do not have coverage criteria for radiofrequency ablation of uterine fibroids. Medicare does not have an NCD for radiofrequency ablation of uterine fibroids. National Government Services, Inc. is the Part A/B Medicare Administrative Contractor (MAC) with jurisdiction in the Plan's service area. National Government Services, Inc. does not have an LCD for radiofrequency ablation of uterine fibroids (Medicare Coverage Database search 05/24/2025), therefore, Fallon Health Clinical Coverage Criteria are applicable.

MassHealth Variation

Ultrasound-guided laparoscopic (CPT 58674) and transcervical (CPT 58580) radiofrequency ablation of symptomatic uterine fibroids are covered for MassHealth members meeting the medical necessity criteria listed below.

Effective 06/01/2025, prior authorization is not required for ultrasound-guided laparoscopic (CPT 58674) and transcervical (CPT 58580) radiofrequency ablation of symptomatic uterine fibroids.

Medical record documentation supporting medical necessary includes all of the following:
1.) the primary diagnosis name(s) and the ICD-CM code(s) for the condition,
2.) the secondary diagnosis name(s) and ICD-CM code(s) pertinent to any comorbid conditions, if present,
3.) the most recent medical evaluation, including a summary of the medical history and the most recent physical exam with emphasis on findings relevant to uterine fibroids including an abdominal and pelvic exam,
4.) results of radiology studies (ultrasound, MRI, etc.) and other tests relevant to the condition for which radiofrequency ablation is being performed,
5.) a summary of the nonoperative, conservative treatment(s) that have been tried and have been unsuccessful in managing the patient's condition,
6.) any risk factors and/or comorbid conditions the member has provided informed written consent.

Summary of Evidence

Uterine fibroids (also called uterine myomas, fibromyomas or leiomyomas) are the most common benign tumors in women and are the leading reason for hysterectomy. Fibroids may be single or multiple and can vary in size and location. A standardized classification system was developed by the International Federation of Gynecology and Obstetrics (FIGO). Most uterine fibroids are asymptomatic, diagnosed incidentally on clinical examination or imaging and will not require treatment. Prolonged or heavy menstrual bleeding, with or without anemia and the sequelae of uterine enlargement are the most common presenting symptoms (ACOG, 2021). Surgery, including hysterectomy and myomectomy, and uterine artery embolization are considered the criterion standard for symptom resolution. However, there is the potential for surgical complications, and, in the case of a hysterectomy, the uterus is not preserved. There has been longstanding research interest in developing minimally invasive alternatives for treating uterine fibroids, including procedures that retain the uterus and permit future childbearing.

Laparoscopic
The U.S. Food and Drug Administration (FDA) cleared the Acessa System (originally Halt Medical, Inc., acquired by Hologic, Inc.) through the 510(k) process (K121858) for use in percutaneous coagulation and ablation of soft tissue under laparoscopic ultrasound guidance, including treatment of symptomatic uterine fibroids. 510k FDA product code: HFG. The technology was previously approved in 2010, at which time it was called the Halt 2000GI™ Electrosurgical Radiofrequency Ablation System.

The American College of Obstetricians and Gynecologists (ACOG, 2021) guideline on management of symptomatic uterine leiomyomas included the following Level B recommendation (recommendation based on limited or inconsistent scientific evidence), "*Laparoscopic radiofrequency ablation can be considered as a minimally invasive treatment option for the management of symptomatic leiomyomas in patients who desire uterine preservation and are counseled about the limited available data on reproductive outcomes*". The guideline noted that "*laparoscopic RFA with a leiomyoma specific FDA-approved device has been studied primarily in nonrandomized trials*" and the recommendation was based in part on recent meta-analyses, Bradley (2019) and Lin (2019), discussed below. The guideline provides three Level A recommendations (recommendations based on good and consistent scientific evidence):

- Gonadotropin-releasing hormone (GnRH) agonists, either with or without add-back hormonal therapy, are recommended for the short-term treatment of AUB-L [Abnormal Uterine Bleeding associated with Leiomyomas] and uterine enlargement associated with uterine leiomyomas and as a bridge to other treatment strategies.
- Uterine artery embolization (UAE) is recommended as an interventional procedure for the treatment of uterine leiomyomas in patients who desire uterine preservation and are counseled about the limited available data on reproductive outcomes.
- When hysterectomy is selected for the surgical management of symptomatic uterine leiomyomas, the most minimally invasive route is recommended whenever possible, and the vaginal approach is preferred among the minimally invasive approaches when it is feasible.

Lin et al., 2019 conducted a meta-analysis to assess the short-term (3 and 6 months) and long-term (12, 24, and 36 months) symptom relief and quality of life improvement, procedure-related adverse event rate,

reintervention rate, and days missed from work after laparoscopic radiofrequency ablation. The review included 1 RCT (interim analysis only with high loss to follow-up) and 7 non-comparative trials with a total of 581 patients. Based on validated questionnaires, quality of life improved significantly until 36 months after laparoscopic radiofrequency ablation therapy, with a maximum improvement (Health-Related Quality of Life [HRQL] questionnaire score of +41.64 [95% confidence interval (CI), 38.94-44.34] and a transformed Symptom Severity Score [SSS] of -39.37 [95% CI, 34.70-44.04]) at 12 months after laparoscopic radiofrequency ablation. All subscales of quality of life improved significantly, and most of the changes remained stable in long-term follow-up. The overall reintervention rate was 4.39% (95% CI, 1.60%-8.45%), and the median uterine volume reduction was 69.17 cm^3 (95% CI, 35.87-102.46 cm^3).The overall procedure-related adverse events rate was 1.78% (95% CI, 0.62%-3.53%), and patients missed an average of 4.35 days (95% CI, 2.55-6.15 days) of work. The authors concluded that laparoscopic radiofrequency ablation therapy is an efficacious way to treat small-sized and nonpedunculated symptomatic uterine fibroids, providing stable long-term symptom relief and quality of life improvement with a low risk of adverse events and reintervention and just a few days of missed work.

Bradley and colleagues conducted a systematic review of prospective studies for treatment of uterine fibroids with radiofrequency ablation (RFA). Thirty-two articles involving 1283 unique patients (median age: 42 years) treated with laparoscopic RFA (19 articles), transvaginal RFA (8 articles), or transcervical fibroid ablation (5 articles). RFA was delivered using ultrasound guidance in 90% of the studies. The weighted mean procedure time was 49 minutes (95% CI: 41–56 minutes). Procedure time was significantly different among RFA delivery approaches (laparoscopic, 73 minutes; transcervical, 44 minutes; transvaginal, 24 minutes), where all pairwise comparisons were $P \leq .002$. Following RFA, mean fibroid volume decreased by 47% at 3 months, 55% at 6 months, 66% at 12 months, and 71% at >12 months follow-up. Fibroid symptoms, where lower SSS scores indicate lower symptom severity, decreased by 29, 36, 42, and 40 points relative to baseline over this same period (all $P < .001$ versus baseline). The cumulative rate of surgical reinterventions for fibroid-related symptoms was 4.2%, 8.2%, and 11.5% at annual follow-up intervals through 3 years.

In 2013, Chudnoff et al. published 3, 6 and 12 month results of a prospective single-arm study (Clinicaltrials.gov NCT00874029) including 137 subjects with documented symptomatic uterine fibroids and confirmed heavy menstrual bleeding (≥ 160 to ≤ 500 mL). Baseline MRI was used to establish fibroid number and size and to exclude adenomyosis and type 0 submucosal myomas. The three primary end points were volume of menstrual bleeding at 12 months compared to baseline, surgical re-intervention rate for heavy menstrual bleeding at 12 months, and device and procedure-related adverse events within 12 months. Secondary endpoints were uterine volume measurements, UFS-QOL scores, overall treatment evaluation scores, and general health outcome scores at 12 months. Menstrual blood loss fell in 81.9 % of subjects with a decrease of at least 50 % in 40.2% of subjects and 22 % in 67.7 %. There was one surgical re-intervention for persistent bleeding and one serious adverse event. Total mean myoma volume decreased 45.1 % from baseline. Ninety-four percent of subjects were satisfied with their treatment.

In 2014, Berman et al. reported the three-year findings of the same clinical trial. For 104 evaluable participants with 36-month data, change in mean (SD) symptom severity from baseline (60.2 [18.8]) to 36 months was -32.6 (95% confidence interval, -37.5 to -27.8; $p < .001$). Health-related quality of life also was improved, from the baseline value of 39.2 (19.2) to 38.6 (95% confidence interval, 33.3 to 43.9; $p < .001$) at 36 months. The cumulative re-intervention rate for fibroid symptoms was 11 %. Seven of the fourteen patients who had another procedure were found to have adenomyosis. All subscale UFS-QOL scores and all health state scores remained stable compared to one-year results indicating durability.

Brucker et al., 2014, conducted a randomized controlled trial (RCT) comparing the outcomes of laparoscopic treatment of fibroids by myomectomy or radiofrequency ablation with the Acessa System (ClinicalTrials.gov: NCT01750008). Of 110 patients assessed for eligibility, 51 were randomized to the 2 interventions; the final analysis included 25 patients in the RFA group and 25 patients in the myomectomy group. The primary objective of the present study was to compare the mean time to discharge from the hospital following laparoscopic treatment of fibroids by myomectomy or RFA. The secondary objective was to compare perioperative outcomes. A 5-year follow-up is planned to study long-term outcomes, such

as pregnancy, symptom improvement, recurrence or regrowth of myomas, and reintervention rates. The mean hospitalization times were 10.0 ± 5.5 (median 7.8 [range 4.2–25.5]) hours for the RFA group and 29.9 ± 14.2 (median 22.6 [range 16.1–68.1]) hours for the myomectomy group (P < 0.001, Wilcoxon test). Intraoperative blood loss was 16 ± 9 (median 20 [range: 0–30]) mL for the RFA procedures and 51 ± 57 (median 35 [range 10–300]) mL for the myomectomy procedures. The percentage of fibroids imaged by laparoscopic ultrasound that were treated/excised was 98.6% for RFA and 80.3% for myomectomy. Two complications were reported: vertigo (n = 1; RFA) and port site hematoma (n = 1; myomectomy). Radiofrequency ablation resulted in the treatment of more fibroids, a significantly shorter hospital stay, and less intraoperative blood loss than laparoscopic myomectomy.

Hahn et al., 2015 reported 3-, 6-, and 12-month outcomes in terms of pain medication use, recovery from surgery, and subjects subjective responses to validated questionnaires for Brucker et al. 2014 (ClinicalTrials.gov: NCT01750008). The use of post-surgical pain medication, missed workdays , resumption of normal activities were not significantly different between groups. Mean SSS scores decreased (improved) by −7.8 for the RFA subjects and by −17.9 for the myomectomy subjects (p = 0.16). Health-related quality of life improved (increased) by 7.5 and 13.1, respectively, for the two groups (p = 0.46). The surgeons incorporated intraoperative laparoscopic ultrasound not only to detect the uterine fibroids, but to measure the sum of their major diameters. For those women in the RFA group, the mean sum of major diameters at baseline was 7.7 ± 4.2 cm; for those women randomized to myomectomy, the mean sum was 6.6 ± 3.2 cm. For those fibroids that were present and measurable at 12 months in the 19 subjects in each group, the mean sum of the major diameters was 4.8 ± 2.8 cm for the 15 fibroids detected in those women in the ablation group and 4.2 ± 2.6 cm for the 3 residual fibroids detected in those women in the myomectomy group. Two myomectomy subjects had pregnancies that ended in a Cesarean delivery and a vaginal delivery of healthy infants. Two pregnancies in the RFA group ended in full-term vaginal deliveries of healthy infants.

Kramer et al., 2016 reported on 24 month data from Brucker, et al., 2014 (ClinicalTrials.gov: NCT01750008). At 24 months, 21 patients in the RFA group and 22 patients in the laparoscopic myomectomy were available for analysis. Significant improvements in symptom severity from baseline (indicated by decreasing values) were recorded in the RFA (−54% [95% CI −72.3 to −34.8]; P b 0.001) and laparoscopic myomectomy (−45% [95% CI −68.9 to −20.9]; P = 0.001) groups. An improvement from baseline (indicated by increasing values) in health-related quality-of-life scores were reported for the laparoscopic myomectomy group (21% [95% CI 1.1 to 40.5]; P = 0.040); a non-significant improvement was observed in the RFA group (11% [95% CI −1.6 to 23.0]; P = 0.083). Participants in the laparoscopic myomectomy group had higher symptom severity and lower quality of life than patients in the RFA group at baseline. A significant improvement in health-related quality of life was observed in the laparoscopic myomectomy group (P = 0.040); a non-significant improvement was recorded in the RFA group (P = 0.083). In the RFA group, two patients underwent hysterectomy, and one patient underwent myomectomy during the follow-up period. No participants in the laparoscopic myomectomy group sought surgical re-intervention owing to fibroid symptoms. In the RFA group, three patients conceived; two pregnancies concluded with vaginal deliveries of healthy neonates and one pregnancy resulted in a cesarean delivery of a healthy neonate. In the laparoscopic myomectomy group, six conceptions were experienced by a total of five patients. Of these, one induced abortion, two vaginal deliveries, and two cesarean deliveries were recorded, with one pregnancy ongoing at the time of writing.

The Treatment Results of Uterine Sparing Technologies (TRUST) is a Canadian post-market RCT comparing laparoscopic RFA with laparoscopic myomectomy and uterine artery embolization for the treatment of symptomatic fibroids. Results of the TRUST study (NCT01563783) were published by Rattray et al., 2018. The consent process included the participant's willingness to be randomized (1:1) to one of two groups as follows: Group 1 offered randomization to either laparoscopic RFA or myomectomy, whereas Group 2 offered randomization to either Lap-RFA or uterine artery embolization UAE. A total of 51 subjects provided written informed consent and enrolled between October 2012 and June 2017. Three subjects withdrew consent prior to treatment and opted for a hysterectomy. The investigator withdrew one subject due to a finding of adenomyosis without any fibroids found during laparoscopic ultrasound. Only two subjects were recruited into Group 2 (laparoscopic RFA: n=1; UAE: n=1). Therefore, the analysis was confined to Group 1 participants only, with a total of 45 subjects enrolled into Group 1 (Lap-RFA: n=23;

myomectomy: n=22). The primary endpoint of the study was the mean total hospitalization time for subjects in each treatment group. Hospitalization time (primary endpoint) was 6.7±3.0 hours for the laparoscopic RFA group and 9.9±10.7 hours for the myomectomy group (Wilcoxon, p=0.0004). Mean intraoperative blood loss was significantly lesser for the subjects undergoing laparoscopic RFA than for those undergoing myomectomy: 25.2±21.6 versus 82.4±62.5 mL, respectively (p=0.0002). The total and mean numbers of fibroids treated and excised, respectively, were 79 (mean: 3.4±2.4 for laparoscopic RFA) and 61 (mean: 2.8±2.4 for myomectomy). At their 3 months follow-up, participants from both cohorts reported the same significant reduction (−44.8%) in symptom severity from their baseline scores: laparoscopic RFA: 95% CI: −39.9, −16.6 (p<0.0001) and myomectomy: 95% CI: −37.2, −15.0 (p<0.0001). The laparoscopic RFA group reported a greater percentage improvement over baseline in their health-related quality of life than did the myomectomy group: 62.2% versus 45.8%, respectively. However, improvement over baseline in both groups was statistically significant (p=0.0009 and p=0.0001, respectively).

Transcervical
Sonata® Sonography-Guided Transcervical Fibroid Ablation System (Gynesonics, Inc., Redwood City, CA) received FDA 510(k) clearance on August 15, 2018 (K173703), Product Code: KNF. Sonata® Sonography-Guided Transcervical Fibroid Ablation System 2.1 received FDA 510(k) clearance on May 4, 2020 (K193516), and Sonata® Transcervical Fibroid Ablation System 2.2 received FDA 510(k) approvals on June 17, 2021 (K211535), November 8, 2022 (K222304), and December 21, 2023 (K233848). Sonata® Transcervical Ablation System is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.

The published evidence is comprised of 3 prospective, multicenter, single-arm cohort studies (FAST-EU trial, SONATA trial and OPEN trial) and one retrospective data collection study (VITALITY). Two studies (SONATA and OPEN) evaluated the Sonata System, and two studies (FAST-EU and VITALITY) evaluated its predecessor device (VizAblate System). In total, 234 women were enrolled in the 3 prospective studies. VITALITY enrolled 23 women who were previously treated in FAST-EU.

Lukes and Green (2020), Miller and Osman (2019) and Chudnoff et al. (2019), reported on the outcomes of the SONATA trial (NCT02228174), a prospective, multicenter, single-arm cohort study (intervention = Sonata System, no comparator) that evaluated the safety and effectiveness of the Sonata System in the treatment of symptomatic uterine fibroids. Premenopausal women (n = 147) between the ages of 25 and 50 years with symptomatic uterine fibroids between 1-5 cm in diameter were enrolled. The study was conducted at 22 sites (21 in the United States, 1 in Mexico). Key exclusion criteria included desire for future pregnancy. Following the procedure, patients returned at 10 days, 30 days, 3 months, 6 months, and annually thereafter through the final follow-up visit at 3 years. The 24- and 36-month follow-up timepoints were included to gather longer-term data during the post-market phase and were not included to support the application for FDA clearance. Lukes (2020) reported on the 3-year outcomes, Miller and Osman (2019) on the 2-year outcomes and Chudnoff et al. (2019) on the 12-month outcomes. The study met its co-primary endpoints at 12 months (n=143, full analysis set), with 64.8% of women experiencing 50% or greater reduction in menstrual bleeding and 99.3% of women who did not have surgical intervention for heavy menstrual bleeding. The mean pictorial blood loss assessment chart score decreased by 38.9%, 48.4%, and 51.1% at 3, 6, and 12 months after the procedure, respectively (p<0.001). At 12 months, 95.1% of women had experienced a reduction in menstrual bleeding. The mean maximal reduction in fibroid volume per patient was 62.4% (p<0.001). Two serious procedural-related AEs were reported in 2 women (1.4%). There were 85% of women enrolled who returned for follow up at 2 years. Over 2 years, surgical reintervention for heavy menstrual bleeding was done in 5.5% of women. There was 1 pregnancy with a normal peripartum outcome. There were 15 women lost to follow up during the trial, with 90% of women accounted for at 3 years (132 people out of 147). Compared with baseline, mean symptom severity scores decreased from 55 (plus or minus 19) to 22 (plus or minus 21), health-related quality of life increased from 40 (plus or minus 21) to 83 (plus or minus 23). EQ-5D increased from 0.72 (plus or minus 0.21) to 0.88 (plus or minus 0.16; all statistically significant with p<0.001). 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. Surgical reinterventions included 10 hysterectomies and 1 endometrial ablation. All work productivity and activity level parameters improved significantly during the

3-year follow up. At 3 years, 94% of women were satisfied with treatment (71% very satisfied, 14% moderately satisfied, 9% somewhat satisfied).

Brölmann et al. (2016) reported on the FAST-EU trial (NCT01226290), a prospective, multicentre, single-arm cohort study (intervention = VizAblate System, no comparator) of 50 women (aged 28 or older) with uterine fibroids and heavy menstrual bleeding. This study was conducted at 7 sites (1 in Mexico, 4 in the Netherlands and 2 in the UK). Total fibroid volumes were reduced from baseline by an average of 55% (49 women; 89 fibroids) and 67% (28 women; 43 fibroids), respectively ($p<0.001$ for all compared with baseline). At 12 months, mean menstrual pictogram scores and symptom severity scores decreased by 54% (n=48; $p<0.001$) and 55% (n=49; $p<0.001$), respectively. This was a single-arm study, so direct comparisons with alternative treatment options cannot be made. Only 58% of eligible patients (28 people out of 48) had MRI at 12 months. Follow-up time was limited to 1 year, so long-term effects are unclear. Women who wanted to have a baby in the future or had fibroids larger than 5 cm were not included. The preservation of uterine wall integrity 12 months after treatment with VizAblate was also assessed for the 29 women using baseline and 12-month MRI image data. This secondary analysis (the INTEGRITY study, Bongers et al. 2019) showed that there were no areas on the MRI that indicated loss of myometrial integrity compared with baseline.

Bongers et al. (2019) conducted a prospective, multicentre, single-arm cohort study (the OPEN trial) to document the incidence of uterine adhesions after transcervical fibroid ablation of symptomatic uterine fibroids with the Sonata system. A total of six sites enrolled 37 patients. There were 50 fibroids with a mean diameter of 3.4 (plus or minus 1.8 cm; ranging from 1 cm to 8 cm) ablated. Of the 37 people enrolled, 35 completed the study follow up and 2 electively withdrew from the study prior to the completion of study follow-up. Thirty-four out of 35 people who had paired baseline and second-look hysteroscopies that could be evaluated by the independent readers. At 6 weeks, none of these hysterectomy videos revealed any formation of intrauterine adhesions after treatment with Sonata. These results suggest the potential for adhesiogenesis after TFA, including in women with apposing submucous and/or transmural myomata, may be minimal. This study included 6 people with apposing fibroids, that usually have a substantial risk of forming adhesions after operative hysteroscopic treatment.

Shifrin et al. (2021) conducted a subgroup analysis of 197 people (534 treated fibroids) from 2 prospective clinical trials (FAST-EU and SONATA) who had submucous, or large fibroids treated with the Sonata (or VizAblate) system. In the study, 86% of people with submucous fibroids only and 81% of people with large fibroids (over 5 cm in diameter) experienced bleeding reduction within 3 months after treatment with the Sonata system. During the 12 months after the procedure, overall symptom severity and health-related quality of life showed sustained, significant improvements. MRI imaging of fibroids in the FAST-EU trial showed an average volume reduction of 68%. Among people with submucous fibroids only, the rate of surgical reintervention during 12 months of follow-up was 3.7% in the FAST-EU trial and 0% in the SONATA trial.

Garza-Leal (2019) conducted a retrospective, single-arm, long-term (> 5 years) data-collection cohort study (VITALITY) involving 23 women with heavy menstrual bleeding secondary to fibroids. The study enrolled women who had previously been enrolled and treated in the 12-month FAST-EU trial at a site in Mexico. The study generated long-term follow-up information from 17 women (73.9%), with a mean follow up of 64.4 months (range 57 to 73 months). From baseline, mean Symptom Severity Score (SSS) decreased significantly from 64.9 ± 16.9 to 27.6 ± 36.1, and mean HRQoL improved significantly from 27.2 ± 22.4 to 76.0 ± 32.6 ($p = 0.002$, and $p = 0.0001$, respectively). There were no surgical reinterventions through the first 3.5 years post-treatment. There was an 11.8% incidence of surgical reinterventions over 5.4 years of average follow-up, with 2 hysterectomies occurring after 3.5- and 4-years post-ablation, respectively (event rate: 2.2% per year; 95% confidence interval; 0.3%, 7.9%). Freedom from surgical reintervention at 1, 2, and 3 years was 100%, and, at 4 and 5 years, was 88.2% ± 7.8%. There was a single pregnancy occurring within the first year of treatment leading to a normal-term delivery by elective repeat cesarean section.

Overall, the evidence suggests that the Sonata System is an effective option for the treatment of symptomatic fibroids, including those associated with heavy menstrual bleeding. Data from the FAST-EU

trial and the SONATA trial reported that using the Sonata System resulted in statistically significant reductions in total and perfused uterine fibroid volume, menstrual bleeding and symptom severity, and improved health-related quality of life. In the SONATA trial, there was a low rate of surgical reintervention during the first 12 months after treatment and no device-related adverse events were recorded (Chudnoff et al. 2019). The evidence base suggests that on average people return to normal daily activities between 2 and 4 days after the procedure and are generally satisfied with treatment. In the SONATA trial (Lukes et al. 2020) 94% of people were very, moderately or somewhat satisfied with treatment at 3 years. Data from the OPEN clinical trial suggests that using the technology has little or no risk of causing intrauterine adhesions (Bongers et al. 2019). Longer-term follow-up data from a small cohort of FAST-EU trial patients (Garza-Leal 2019) suggests that some of the clinical benefits of the technology (reduced symptoms and improved quality of life) can last more than 5 years after treatment.

SAGE is a post-market global registry (NCT03118037) with the objective of characterizing long term outcomes after treatment of uterine fibroids with the Sonata® System in real world clinical practice settings. Patients will be followed for 5 years. Patient recruitment began in June 2017. Primary outcomes include the incidence of pregnancy and pregnancy outcomes, and surgical reintervention for heavy menstrual bleeding. Secondary outcome measures include symptom severity and quality of life are assessed with the symptom severity score (SSS) and health-related quality of life (HRQL). The estimated study completed date for SAGE is December 2028. Per ClinicalTrials.gov website, SAGE (NCT03118037) was terminated on November 11, 2024 due to continued lack of patient compliance.

Analysis of Evidence (Rationale for Determination)

Laparoscopic and transcervical radiofrequency ablation (RFA) are considered minimally invasive treatment options for the management of symptomatic uterine fibroids in patients who desire fertility preservation.

The evidence for laparoscopic RFA using the Acessa System consists of prospective single-arm studies, RCTs comparing RFA with laparoscopic myomectomy and meta-analysis. The meta-analysis found low rates of reintervention with laparoscopic RFA at 24 months (4.4%). Improvements in symptoms and quality of life were maintained out to 24 months in 3 studies and out to 36 months in 1 study. Two RCTs found that RFA was noninferior to laparoscopic myomectomy on the primary outcome (length of hospitalization). A number of secondary outcomes for one RCT were reported at 12 and 24 months, including symptoms and quality of life outcomes; none differed significantly between groups. The RCT only had 43 patients in subgroup analyses at 12 and 24 months and may have had insufficient power for the secondary outcomes. Laparoscopic RFA is associated with a reduction in symptoms and improvement in quality of life in the short-term. The reintervention rate at longer follow-up is unknown. Because most trials excluded women who desired to become pregnant, the impact of RFA on pregnancy outcomes is uncertain. Additional well-designed comparative trials with longer follow-up are needed to determine the effect of laparoscopic RFA on health outcomes compared with other treatment options, including myomectomy.

For individuals who have symptomatic uterine fibroids who receive ultrasound-guided transcervical radiofrequency ablation using the Sonata® Transcervical Fibroid Ablation System (Gynesonics, Inc., Redwood City, CA), the evidence consists of three prospective cohort studies and one retrospective data collection study. All available evidence came from single-arm studies only, so direct comparisons with alternative treatments for fibroids cannot be made. Long-term data is available from 2 studies: one retrospective, single-arm, long-term (> 5 years) data collection study from a small cohort of patients (n=17) (Garza-Leal, 2019), and 3-year follow-up data from 132 of 147 women who were enrolled in the SONATA trial. Larger, long-term head-to-head studies comparing the technology with standard care (that is, myomectomy, hysterectomy, or uterine artery embolization) are needed. In most of the studies, the treatable fibroids were limited to those that were between 1 cm and 5 cm in diameter, because these would normally be treated with one ablation only. Further evidence is needed on how transcervical RFA may affect fertility for women who want to have children in the future.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Code	Description
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

Category III CPT code 0404T was replaced with new Category I CPT code 58580 effective January 1, 2024.

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Policy history

Origination date:	02/01/2023
Review/Approval(s):	Technology Assessment Committee: 10/25/2022 (policy origination), 04/23/2024 (annual review; criteria unchanged; added Summary of Evidence and Analysis of Evidence (Rationale for Determination), 04/29/2025 (annual review; added new sections for Medicare and MassHealth Variation; updated MassHealth Variation to include coverage and criteria for laparoscopic radiofrequency ablation of uterine fibroids; updated Summary of Evidence to include clinical studies related to laparoscopic radiofrequency ablation of uterine fibroids; updated References). Utilization Management Committee: 05/20/2025: (annual review; approved).

Instructions for Use

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Fallon Health generally follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.

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