Ultrasound-Guided Transcervical Radiofrequency Ablation of Uterine Fibroids Clinical Coverage Criteria

Description

This policy applies specifically to ultrasound-guided 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)

Ultrasound-guided transcervical radiofrequency ablation of uterine fibroids requires prior authorization.

Medicare Advantage
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).

Medicare statutes and regulations do not have coverage criteria for ultrasound-guided transcervical radiofrequency ablation of uterine fibroids. Medicare does not have an NCD for ultrasound-guided transcervical radiofrequency ablation of uterine fibroids. National Government Services, Inc. is the Part A/B Medicare Administrative Contractor (MAC) with jurisdiction in our service area. National Government Services, Inc. does not have an LCD or LCA for ultrasound-guided transcervical radiofrequency ablation of uterine fibroids (Medicare Coverage Database search 04/22/2024), therefore, Fallon Health Clinical Coverage Criteria are applicable.

MassHealth
Fallon Health 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.

In June 2022, MassHealth issued **Transmittal Letter PHY-164**, adding coverage for Sonata® Transcervical Fibroid Ablation (CPT code 0404T), effective June 1, 2022, for MassHealth members with uterine fibroids who meet clinical criteria outlined in Transmittal PHY-164.

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

NaviCare HMO SNP, NaviCare SCO
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.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
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.

Fallon Health Clinical Coverage Criteria

Commercial, Fallon Medicare Plus, Fallon Medicare Plus Central and Fallon Health Weinberg PACE

Fallon Health considers ultrasound-guided transcervical radiofrequency ablation of uterine fibroids using the Sonata® Transcervical Fibroid Ablation System (Gynesonics, Inc., Redwood City, CA) experimental and investigational.

A service that is considered experimental and investigational is not medically necessary (not reasonable and necessary) and is therefore not covered.

MassHealth ACO, NaviCare and Summit Eldercare PACE

Ultrasound-guided transcervical radiofrequency ablation of symptomatic uterine fibroids using the Sonata® Transcervical Fibroid Ablation System (Gynesonics, Inc., Redwood City, CA) is covered for MassHealth ACO, NaviCare and Summit PACE members effective June 1, 2022, in accordance with MassHealth Transmittal Letter PHY-164.

Prior authorization is required for ultrasound-guided transcervical radiofrequency ablation of uterine fibroids using the Sonata Transcervical Fibroid Ablation System (CPT58580) effective for dates of service on or after March 1, 2023.

Requests for Sonata Transcervical Fibroid Ablation (58580) must be accompanied by clinical documentation that supports medical necessary, including 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 Sonata is being requested,

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' and
7.) other pertinent information that the Plan may request.

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.

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) involving 37 women to document the incidence of uterine adhesions after transcervical fibroid ablation of symptomatic uterine fibroids with the Sonata system. 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. 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. This 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 an ongoing 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. The results of SAGE will strengthen the existing evidence base for Sonata (Christoffel et al., 2021).

Analysis of Evidence (Rationale for Determination)

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 1 ablation only. In the SONATA study, 14.5% of fibroids (less than 5 cm in diameter) were treated with 2 or more ablations (Chudnoff et al. 2019). Data on the treatment of larger fibroids (over 5 cm in diameter) with Sonata® is available (Shifrin et al. 2021). This study reported that Sonata® is an effective single-stage treatment option for nonpedunculated submucous fibroids, and larger or deeper uterine fibroids (including fibroid clusters), for which hysteroscopic treatment is not suitable. In a retrospective analysis, Piriyev et al., 2022 reported on the effectiveness of transcervical radiofrequency ablation of fibroids that are 5 cm or larger using the Sonata® System. The smallest fibroid was 4 cm, and the largest fibroid was 12 cm. A single ablation was performed in

18 cases, two ablation steps in 16 cases, three ablation steps in 13 cases, and more than three ablation steps in three cases.

Studies excluded women who may want to have children in the future. The 12-month MRI data from 34 women in the FAST-EU trial (Bongers et al. 2019) showed that treatment with Sonata® may preserve uterine wall integrity. Successful pregnancies (36 pregnancies representing 20 deliveries among 28 women) after treatment with the Sonata System have been reported (Christoffel et al., 2022). Further evidence is needed on how Sonata 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

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

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Policy history

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