

## Medical Policy

### Radiofrequency Ablation to Treat Uterine Fibroids

**Policy Number: 050**

|                        | Commercial and Qualified Health Plans | Mass General Brigham ACO | Medicare Advantage | OneCare      | Senior Care Options (SCO) |
|------------------------|---------------------------------------|--------------------------|--------------------|--------------|---------------------------|
| Authorization Required | X                                     | X                        | X<br>(58580)       | X<br>(58580) | X<br>(58580)              |
| No Prior Authorization |                                       |                          | X<br>(58674)       | X<br>(58674) | X<br>(58674)              |

#### Overview

The purpose of this document is to describe the guidelines Mass General Brigham Health Plan utilizes to determine the medical necessity for laparoscopic or transcervical radiofrequency ablation to treat uterine fibroids. The treating specialist must request prior authorization for the procedure.

#### Coverage Guidelines

##### Initial Treatment

The use of an FDA approved device to destroy uterine fibroids through laparoscopic or transcervical ultrasound-guided radiofrequency ablation (e.g., Acessa™ or Sonata™) may be considered medically necessary when the member has one or more of the following symptoms directly attributed to uterine fibroids:

1. Excessive menstrual bleeding (menorrhagia); or
2. Urinary symptoms or gastrointestinal symptoms (e.g., urinary frequency, abdominal bloating, constipation); or
3. Pelvic pain; or
4. Lower back pain; or
5. Painful sexual relations (dyspareunia).

##### Exclusions

1. Fibroid size greater than 9 cm for Acessa and greater than 7 cm for Sonata. Exceptions to this exclusion will be considered on an individual basis by a Medical Director.
2. The member has an acute pelvic infection; or
3. The member has a diagnosis of gynecological cancer or a pre-cancerous lesion (e.g., atypical endometrial hyperplasia, leiomyosarcoma, etc.); or
4. The member has an abnormal pap smear test result without appropriate follow-up; or
5. The member is currently pregnant; or
6. Presence of an intrauterine device (IUD), unless removed prior to the introduction of the Sonata Treatment Device; or

7. Techniques for myolysis using energy sources other than radiofrequency ablation.

#### Medicare Variation

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for medical necessity determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. **As of Mass General Brigham Health Plan's most recent policy review, CMS had no NCDs/LCDs for radiofrequency ablation to treat uterine fibroids.**

#### MassHealth Variation

Mass General Brigham Health Plan uses guidance from MassHealth for medical necessity determinations for its Mass General Brigham ACO members. When there is no guidance from MassHealth for the requested service, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. **At the time of Mass General Brigham Health Plan's most recent policy review, MassHealth did not have medical necessity guidelines for radiofrequency ablation to treat uterine fibroids.**

#### OneCare and SCO Variation

Mass General Brigham Health Plan uses guidance from CMS for medical necessity determinations for its OneCare and SCO plan members. NCDs, LCDs, LCAs, and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan uses medical necessity guidelines from MassHealth. When there is no guidance from CMS or from MassHealth, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations.

#### Definitions

Laparoscopic Ultrasound-Guided Radiofrequency Ablation: A minimally invasive procedure that uses a laparoscopic ultrasound probe to determine the location and size of fibroids. Then a small electrode array delivers radiofrequency energy to destroy the fibroids.

Transcervical Radiofrequency Ablation: A minimally invasive procedure that integrates intrauterine ultrasound imaging with radiofrequency transcervical incisionless treatment to destroy uterine fibroids.

#### Codes

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

| Authorized CPT/HCPCS Codes | 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 |

#### Summary of Evidence

The Sonata and Acessa radiofrequency ablation (RFA) treatments for uterine fibroids have been evaluated in several single-arm interventional trials. The single-arm prospective HALT trial (Chudnoff et al. 2013, Guido et



al. 2013, Berman et al. 2014) demonstrated that laparoscopic volumetric RFA of fibroids with the Acessa system resulted in significant improvements in symptom scores, blood loss, and quality of life compared with baseline at 1, 2, and 3 years of follow-up, with a re-intervention rate of 11% at 3 years. The FAST-EU trial (Brölmann et al. 2016), also a single-arm prospective trial, showed that transcervical ultrasound-guided RFA using the Sonata system (previously known as Vizablate) also produced significant improvements in fibroid volume, menstrual symptoms, and quality of life at 1 year of follow up. The INTEGRITY trial (Bongers et al. 2019), a secondary analysis of the FAST-EU trial, provided MRI evidence that uterine wall integrity was maintained after transcervical ablation. The SONATA trial (Chudnoff et al. 2019, Miller and Osman 2019, Lukes et al. 2020) was, like FAST-EU, a single-arm prospective trial of the transcervical Sonata system; in this study, improvements in uterine fibroid symptom score and health-related quality of life were maintained through 1, 2, and 3 years of follow-up. Piriyeve (2021) reported on treatment of larger fibroids using the transcervical Sonata system.

An ACOG practice bulletin stated that laparoscopic or transcervical RFA “can be considered as a minimally invasive option” for the management of symptomatic fibroids but emphasizes the limited available data on reproductive outcomes. Meta-analyses by Bradley et al. (2019) and Lin et al. (2018) synthesized evidence from prospective studies on RFA of fibroids. The NICE guidelines (2021) offered recommendations for transcervical ultrasound guided RFA based on patient preference, fibroid size, and symptom severity. A randomized trial by Brucker et al. (2014) suggested that laparoscopic RFA was less invasive than laparoscopic myomectomy, with lower risk of complications, and similar or better outcomes for symptom relief. Real-world outcomes using of transcervical RFA were reported by Christoffel (2021) and van der Meulen (2022) and were generally consistent with prior studies. Brooks (2020) gathered data from a commercial payer claims database, and found that the Sonata system was associated with substantially lower cost to payors than myomectomy or hysterectomy.

Although few randomized studies are available, numerous single-arm prospective studies support the use of RFA devices for the treatment of symptomatic uterine fibroids, particularly when hysteroscopic resection is not feasible and when medical management is not appropriate. Given the good apparent efficacy, favorable safety profile, and favorable cost-effectiveness compared with other therapies, MGB Health Plan considers this therapy to be medically necessary for patients with symptomatic fibroids without contraindications.

### **Effective**

January 2026: Ad-hoc update. Updated prior authorization table and added variation for OneCare and SCO members. Fixed code disclaimer.

March 2025: Annual review. Summary of evidence added. References updated.

December 2024: Ad-hoc update. Clarified Medicare variation. Added MassHealth variation. Fixed prior authorization table at top of policy.

April 2024: Ad-hoc update. Allowed for exceptions to exclusion #1.

March 2024: Annual review.

January 2024: Ad hoc update. Coding update. 0404T code replaced with CPT 58580.

March 2023: Annual review. Medicare Advantage added to table. References updated.

June 2022: Ad-hoc update. Added transcervical radiofrequency ablation as a covered service for MassHealth.

March 2022: Annual Review. References updated.

March 2021: Effective Date.

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