

## Medical Policy

### Radiofrequency Ablation to Treat Uterine Fibroids

**Policy Number:** 050

#### Authorization Requirements

	Commercial and Connector/ Qualified Health Plans	MassHealth	Medicare Advantage
<b>Procedure</b>			
• Laparoscopic radiofrequency ablation	X	X	X
• Transcervical radiofrequency ablation	X	X	X

#### 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)
2. Urinary symptoms or gastrointestinal symptoms (e.g., urinary frequency, abdominal bloating, constipation)
3. Pelvic pain
4. Lower back pain
5. Painful sexual relations (dyspareunia)

##### Exclusions

1. Fibroid size greater than 9 cm for Acessa and greater than 7 cm for Sonata
2. The member has an acute pelvic infection
3. The member has a diagnosis of gynecological cancer or a pre-cancerous lesion (e.g., atypical endometrial hyperplasia, leiomyosarcoma, etc.)
4. The member has an abnormal pap smear test result without appropriate followup
5. The member is currently pregnant
6. Presence of an intrauterine device (IUD), unless removed prior to the introduction of the Sonata Treatment Device
7. Techniques for myolysis using energy sources other than radiofrequency ablation

##### Medicare Variations

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS)

for coverage 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 coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan’s medical policies are used for coverage 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.**

**This list of codes applies to commercial and MassHealth plans only.**

Authorized CPT/HCPCS Codes	Code Description
58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency

**Effective**

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.

**References**

American College of Obstetricians and Gynecologists (ACOG). Alternatives to hysterectomy in the management of leiomyomas. ACOG practice bulletin No. 96. reaffirmed 2019; <http://www.acog.org/-/media/List-of-Titles/PBListOfTitles.pdf>

Berman, J., Guido, R., Gerardo Garza Leal, J., et al. Three years’ outcome from the Halt trial: a prospective analysis of radiofrequency volumetric thermal ablation of myomas, *The Journal of Minimally Invasive Gynecology*. 2014; 21(5):767.

Bongers M, Gupta J, Garza-Leal JG, Brown M, Felberbaum R. The INTEGRITY Trial: Preservation of Uterine-Wall Integrity 12 Months After Transcervical Fibroid Ablation with the Sonata System. *J Gynecol Surg*. 2019 Oct 1;35(5):299-303. doi: 10.1089/gyn.2019.0033. Epub 2019 Oct 4. PMID: 31602171; PMCID: PMC6785167.

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;29:1507-1517.



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.

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;12:1-11

Brucker SY, Hahn M, Kraemer D, et al. Laparoscopic radiofrequency volumetric thermal ablation of fibroids versus laparoscopic myomectomy. *Int J Gynaecol Obstet*. Jun 2014;125(3):261-265. PMID 24698202.

Center for Devices and Radiological Health (CDRH). K121858. Acesa System [substantial equivalence letter]. November 5, 2012. Food and Drug Administration [website]. Available at: [https://www.accessdata.fda.gov/cdrh\\_docs/pdf12/K121858.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf12/K121858.pdf).

Center for Devices and Radiological Health (CDRH). K173703. Sonata Sonography-Guided Transcervical Fibroid Ablation System [substantial equivalence letter]. August 15, 2018. Food and Drug Administration [website]. Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K173703>

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. doi: 10.2147/MDER.S301166. Erratum in: *Med Devices (Auckl)*. 2021 Mar 15;14:85. PMID: 33688276; PMCID: PMC7937398.

Chudnoff S, Guido R, Roy K, Levine D, Mihalov L, Garza-Leal JG. Ultrasound-Guided Transcervical Ablation of Uterine Leiomyomas. *Obstet Gynecol*. 2019;133:13-22.

Fasciani A, Turtulici G, Siri G, Ferrero S, Sirito R. A Prospective Intervention Trial on Tailored Radiofrequency Ablation of Uterine Myomas. *Medicina (Kaunas)*. 2020 Mar 12;56(3):122. doi: 10.3390/medicina56030122. PMID: 32178351; PMCID: PMC7143923.

Guido RS, Macer JA, Abbott K, Falls JL, Tilley IB, Chudnoff SG. Radiofrequency volumetric thermal ablation of fibroids: a prospective, clinical analysis of two years' outcome from the Halt trial. *Health and Quality of Life Outcomes*. 2013;11(1):139.

Hayes, Inc. Hayes Health Technology Brief. Laparoscopic radiofrequency volumetric thermal ablation (Acesa System, Halt Medical Inc.) for treatment of uterine fibroids. Lansdale, PA: Hayes, Inc.; October 2016. Updated November 2017. Updated November 2018.

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

Lindner LH, Roy K, Toub DB. Transcervical fibroid ablation (TFA) with the Sonata System: Updated review of a new paradigm for myoma treatment. *Curr Obstet Gynecol Rep*. 2022;11:238–248.

Lin, LL, Ma, HH, Wang, JJ. Quality of Life, Adverse Events, and Reintervention Outcomes after Laparoscopic Radiofrequency Ablation for Symptomatic Uterine Fibroids: A Meta-Analysis. *J Minim Invasive Gynecol*. 2018 Sep 27;26(3). PMID 30253997

Linda D Bradley, MD, Resad P. Pasic, MD, Larry E Miller, PhD. 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 Nov 8; doi:10.1089/lap.2019.0550



Lukes A, Green MA. Three-Year Results of the SONATA Pivotal Trial of Transcervical Fibroid Ablation for Symptomatic Uterine Myomata. *J Gynecol Surg*. 2020 Oct 1;36(5):228-233.

Management of Symptomatic Uterine Leiomyomas: ACOG Practice Bulletin, Number 228. *Obstet Gynecol*. 2021 Jun 1;137(6):e100-e115. doi: 10.1097/AOG.0000000000004401. PMID: 34011888.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Commonwealth of Massachusetts Executive Office of Health and Human Services, Office of Medicaid: MassHealth Transmittal Letter PHY-164 June 2022, Physician Manual (HCPCS Updates to Subchapter 6).

Miller CE, Osman KM. Transcervical Radiofrequency Ablation of Symptomatic Uterine Fibroids: 2-Year Results of the SONATA Pivotal Trial. *J Gynecol Surg*. 2019;35(6):345-349. doi:10.1089/gyn.2019.0012

National Institute for Health and Care Excellence (NICE). Interventional procedures guidance: Transcervical ultrasound-guided radiofrequency ablation for symptomatic uterine fibroids [IPG689]. March 31, 2021; <https://www.nice.org.uk/guidance/ipg689>. Accessed on February 6, 2023.

Piriyev E, Schiermeier S, Bends R, Römer T. Transcervical radiofrequency ablation of fibroids that are 5 cm or larger in women with abnormal uterine bleeding. *J Gynecol Obstet Hum Reprod*. 2021 Dec 30;51(2):102303. doi: 10.1016/j.jogoh.2021.102303. Epub ahead of print. PMID: 34973479.

Ratray DD, Weins L, Regush LC, Bowen JM, Oreilly D, Thiel JA. Clinical outcomes and health care utilization pre- and post-laparoscopic radiofrequency ablation of symptomatic fibroids and laparoscopic myomectomy: a randomized trial of uterine-sparing techniques (TRUST) in Canada. *ClinicoEconomics and Outcomes Research*. 2018;Volume 10:201–12

Römer T, Bends R, Christoffel L et al. Treatment of symptomatic fibroids with the transcervical ultrasound-guided radiofrequency ablation-indications, implementation, results and complications-expert consensus 2020. Part 2: Transcervical radiofrequency ablation (TRFA) – Method, indications, results and comparison with other therapies. *Frauenarzt* 2021;62:162-168

Roy K, Robinson JK. Durable Improvement in Generic and Fibroid-Specific Quality of Life in Women Treated with Transcervical Fibroid Ablation with the Sonata System After Three Years. *J Gynecol Surg*. 2022 Apr 1;38(2):143-147. doi: 10.1089/gyn.2021.0073. Epub 2022 Apr 1. PMID: 35497488; PMCID: PMC9048174.

Shifrin G, Engelhardt M, Gee P, Pschadka G. Transcervical fibroid ablation with the Sonata™ system for treatment of submucous and large uterine fibroids. *Int J Gynaecol Obstet*. 2021 Oct;155(1):79-85. doi: 10.1002/ijgo.13638. Epub 2021 Mar 17. PMID: 33544889; PMCID: PMC8518813.

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;6:67–73.

van der Meulen JF, Coijmans TH, van Zutven VJ. Et. al. Long-term results of transcervical, intrauterine ultrasound-guided radiofrequency ablation of uterine fibroids with the Sonata System: a retrospective follow-up study. *AJOG Glob Rep*. 2022 Aug 24;2(4):100087. doi: 10.1016/j.xagr.2022.100087. PMID: 36536842; PMCID: PMC9758333.

Yelena Havryliuk, MD, Robert Setton, MD, John Carlow, EdD, MPH, Barry D. Shaktman, MD, Management of symptomatic fibroids: review and meta-analysis of the literature (2006 -2016), *Journal of the Society of Laparoendoscopic Surgeons*, Vol. 21 (3) Jul-Sept 2017

