

**Medical Policy**  
**Radiofrequency Ablation to Treat Uterine Fibroids**

**Authorization Requirements**

	Commercial and Connector/ Qualified Health Plans	MassHealth
<b>Procedure</b>		
• laparoscopic radiofrequency ablation	X	X
• Transcervical radiofrequency ablation	X	Not Covered

**Overview**

The purpose of this document is to describe the guidelines AllWays Health Partners 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
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

## 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.

## CPT/HCPC Codes

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 ( <b>Not covered for MassHealth Plans</b> )

## Effective

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.

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. Accessa 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). Accessed February 16, 2021

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> Accessed February 16, 2021.

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.

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 (Accessa System, Halt Medical Inc.) for treatment of uterine fibroids. Lansdale, PA: Hayes, Inc.; October 2016. Updated November 2017. Updated November 2018.

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.

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

Rattray 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

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.

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

399 Revolution Drive, Suite 810, Somerville, MA 02145 | [allwayshealthpartners.org](http://allwayshealthpartners.org)