

Medical Coverage Policy | Laparoscopic, Percutaneous, and Transcervical Techniques for the Myolysis of Uterine Fibroids & Hysterectomies



EFFECTIVE DATE: 09 | 01 | 2022

POLICY LAST UPDATED: 03 | 01 | 2023

OVERVIEW

Various minimally invasive treatments for uterine fibroids have been proposed as alternatives to surgery. Among these approaches are laparoscopic, percutaneous, and transcervical techniques to induce myolysis, which includes radiofrequency ablation (RFA), laser and bipolar needles, cryomyolysis, and magnetic resonance imaging-guided laser ablation.

This policy also documents the state-mandated hysterectomy coverage guideline amendments to Rhode Island General Law 27-18-44 (Accident and Sickness), Rhode Island General Law 27-19-36.1 (Nonprofit Hospital Service Corporation), Rhode Island General Law 27-29-36.1 (Nonprofit Medical Service Corporation), and Rhode Island General Law 27-41-45.1 (Health Maintenance Organization).

MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

Laparoscopic or transcervical radiofrequency ablation (RFA) as a treatment of symptomatic uterine fibroids is considered medically necessary in individuals 18 years and older when ALL of the following conditions are met:

- Evidence of uterine fibroids via ultrasound that are less than 10 cm in diameter for laparoscopic RFA with Acessa or 7 cm for transcervical RFA with Sonata, AND
- Individual desires a uterine-sparing treatment approach or is ineligible for hysterectomy or other uterine-sparing alternatives to RFA (e.g., laparoscopic myomectomy, uterine artery embolization [UAE]); AND
- Individual has experienced at least 1 of the following symptoms that are a direct result of the fibroid(s):
 - Menorrhagia or other abnormal uterine bleeding that interferes with daily activities or causes anemia;
 - Pelvic pain or pressure;
 - Urinary symptoms (e.g., urinary frequency, urgency) related to bulk compression of the bladder;
 - Gastrointestinal symptoms related to bulk compression of the bowel (e.g., constipation, bloating);
 - Dyspareunia (painful or difficult sexual relations).

PRIOR AUTHORIZATION

Prior authorization is required for Medicare Advantage Plans and recommended for Commercial Products.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Hysterectomies are covered services.

Laparoscopic or transcervical radiofrequency ablation (RFA) procedures must be performed at a certified Obstetrical and Gynecological surgery center.

Laparoscopic or transcervical radiofrequency ablation (RFA) as a treatment of symptomatic uterine fibroids is considered medically necessary when the criteria above are met.

Other laparoscopic, transcervical, or percutaneous techniques for myolysis of uterine fibroids, including use of laser or bipolar needles, cryomyolysis, and magnetic resonance imaging-guided laser ablation, are

considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

Uterine fibroids, also known as leiomyomas, are among the most common conditions affecting individuals in their reproductive years; symptoms include menorrhagia, pelvic pressure, or pain. It is estimated that uterine fibroids occur in up to 70% of individuals by menopause, with approximately 25% of these being clinically significant and requiring intervention. The prevalence rate of uterine fibroids is 2-3 times higher among black individuals compared with white individuals, and there are higher rates of hysterectomy and myomectomy compared with non-surgical therapy, potentially demonstrating a disparity in access to uterine-sparing interventions.

Treatment

Surgery, including hysterectomy and various myomectomy procedures, is 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. In addition, multiple myomectomies may be associated with longer operating time, postoperative febrile morbidity, and development of pelvic adhesions. There has been long-standing research interest in developing minimally invasive alternatives for treating uterine fibroids, including procedures that retain the uterus and permit future childbearing. Treatment options include uterine artery embolization and transcatheter magnetic resonance imaging-guided focused ultrasound therapy. Various techniques to induce myolysis have also been studied including Nd:YAG lasers, bipolar electrodes, cryomyolysis, and radiofrequency ablation. With these techniques, an energy source is used to create areas of necrosis within uterine fibroids, reducing their volume and thus relieving symptoms. Early methods involved multiple insertions of probes into the fibroid, performed without imaging guidance. There were concerns about serosal injury and abdominopelvic adhesions with these techniques, possibly due to the multiple passes through the serosa needed to treat a single fibroid. Newer systems using radiofrequency energy do not require repetitive insertions of needle electrodes. Ultrasonography is used laparoscopically or transcervically to determine the size and location of fibroids, to guide the probe, and to ensure the probe is in the correct location so that optimal energy is applied to the fibroid. Percutaneous approaches using magnetic resonance imaging guidance have also been reported.

Regulatory Status

In 2012, the Acesa™ System (Acesa Health, formerly Halt Medical) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for percutaneous laparoscopic coagulation and ablation of soft tissue and treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance (K121858). The technology was previously approved in 2010, at which time it was called the Halt 2000GI™ Electrosurgical Radiofrequency Ablation System. In 2014, the ultrasound guidance system received marketing clearance from the FDA (K132744). FDA product code: GEI. In 2018, the third-generation Acesa™ ProVu System® was cleared for marketing by the FDA through the 510(k) process for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. (K181124). Hologic acquired Acesa Health in 2020. FDA product code: HFG.

In 2018, the Sonata® Sonography-Guided Transcervical Fibroid Ablation System (Gynesonics) was cleared for marketing by the FDA through the 510(k) process for diagnostic intrauterine imaging and transcervical radiofrequency ablation as treatment of symptomatic uterine fibroids (K173703). The Sonata System 2.1 received marketing clearance in 2020 (K193516) and the Sonata System 2.2 received marketing clearance in 2021 (K211535). The Sonata system was previously known as Vizablate. FDA product codes: KNF, ITX, and IYO.

Cryoablation is a surgical procedure that uses previously approved and available cryoablation systems; and as a surgical procedure, it is not subject to regulation by the FDA. Other products addressed in this review (eg, Nd:YAG lasers, bipolar electrodes) have long-standing FDA approval, and there are no products specifically approved for the treatment of uterine fibroids.

The section of the policy below describes the Hysterectomy coverage guideline amendments to Rhode Island General Law 27-18-44 (Accident and Sickness), Rhode Island General Law 27-19-36.1 (Nonprofit Hospital Service Corporation), Rhode Island General Law 27-29-36.1 (Nonprofit Medical Service Corporation), and Rhode Island General Law 27-41-45.1 (Health Maintenance Organization).

SECTION 1. Chapter 27-18 of the General Laws entitled "Accident and Sickness Insurance Policies" is hereby amended by adding thereto the following section:

27-18-44.1. Hysterectomy or myomectomy treatment.

Commencing January 1, 2023, any insurer or health care healthcare plan, nonprofit health medical service plan, or nonprofit hospital service plan that provides coverage for obstetric and gynecological care for issuance or delivery in the state to any group or individual on an expense-incurred basis, including a health plan offered by a health insurance carrier or a health maintenance organization, shall provide coverage for a hysterectomy, myomectomy and laparoscopic removal of uterine fibroids, including uterine artery embolization, intraoperative ultrasound guidance and monitoring and radiofrequency ablation.

SECTION 2. Chapter 27-19 of the General Laws entitled "Nonprofit Hospital Service Corporations" is hereby amended by adding thereto the following section:

27-19-36.1. Hysterectomy or myomectomy treatment.

Commencing January 1, 2023, any insurer or health care healthcare plan, nonprofit health medical service plan, or nonprofit hospital service plan that provides coverage for obstetric and gynecological care for issuance or delivery in the state to any group or individual on an expense-incurred basis, including a health plan offered by a health insurance carrier or a health maintenance organization, shall provide coverage for a hysterectomy, myomectomy and laparoscopic removal of uterine fibroids, including uterine artery embolization, intraoperative ultrasound guidance and monitoring and radiofrequency ablation.

SECTION 3. Chapter 27-20 of the General Laws entitled "Nonprofit Medical Service Corporations" is hereby amended by adding thereto the following section:

27-20-31.1. Hysterectomy or myomectomy treatment.

Commencing January 1, 2023, any insurer or health care healthcare plan, nonprofit health medical service plan, or nonprofit hospital service plan that provides coverage for obstetric and gynecological care for issuance or delivery in the state to any group or individual on an expense-incurred basis, including a health plan offered by a health insurance carrier or a health maintenance organization, shall provide coverage for a hysterectomy, myomectomy and laparoscopic removal of uterine fibroids, including uterine artery embolization, intraoperative ultrasound guidance and monitoring and radiofrequency ablation.

SECTION 4. Chapter 27-41 of the General Laws entitled "Health Maintenance Organizations" is hereby amended by adding thereto the following section:

27-41-45.1. Hysterectomy or myomectomy treatment.

Commencing January 1, 2023, any insurer or health care healthcare plan, nonprofit health medical service plan, or nonprofit hospital service plan that provides coverage for obstetric and gynecological care for issuance or delivery in the state to any group or individual on an expense-incurred basis, including a health plan offered by a health insurance carrier or a health maintenance organization, shall provide coverage for a hysterectomy, myomectomy and laparoscopic removal of uterine fibroids, including uterine artery embolization, intraoperative ultrasound guidance and monitoring and radiofrequency ablation.

CODING

Medicare Advantage Plans and Commercial Products

The following CPT code(s) is medically necessary for Medicare Advantage Plans and Commercial Products for laparoscopic or transcervical radiofrequency ablation for treatment of symptomatic uterine fibroids when the medical criteria above has been met:

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

CPT codes have not been assigned to all other services or therapies addressed in this policy. These services are considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Product. Therefore, the following Unlisted Procedure code(s) should be used:

58999 Unlisted procedure, female genital system (nonobstetrical)

The following CPT code(s) for Hysterectomies do not require prior authorization and are covered for Medicare Advantage Plans and Commercial Products:

58140 - 58294

58541 - 58554

58570 - 58575

RELATED POLICIES

Magnetic Resonance Imaging Guided Focused Ultrasound
Prior Authorization via Web-Based Tool for Procedures
Unlisted Procedures

PUBLISHED

Provider Update, May 2023

Provider Update, May/August/November 2022

Provider Update, January 2022

Provider Update, November 2020

Provider Update, August 2019

REFERENCES

1. Stewart EA, Adelman MR, Jacoby VL. Management of Symptomatic Uterine Leiomyomas: ACOG Practice Bulletin, Number 228. *ObstetGynecol.* Jun 01 2021; 137(6): e100-e115. PMID 34011888
2. Laughlin-Tommaso SK, Jacoby VL, Myers ER. Disparities in Fibroid Incidence, Prognosis, and Management. *Obstet Gynecol Clin NorthAm.* Mar 2017; 44(1): 81-94. PMID 28160895
3. Stewart EA, Nicholson WK, Bradley L, et al. The burden of uterine fibroids for African-American women: results of a national survey. *JWomens Health (Larchmt).* Oct 2013; 22(10): 807-16. PMID 24033092
4. Jones S, O'Donovan P, Toub D. Radiofrequency ablation for treatment of symptomatic uterine fibroids. *Obstet Gynecol Int.* 2012; 2012:194839. PMID 21961009
5. Davis MR, Soliman AM, Castelli-Haley J, et al. Reintervention Rates After Myomectomy, Endometrial Ablation, and Uterine Artery Embolization for Patients with Uterine Fibroids. *J Womens Health (Larchmt).* Oct 2018; 27(10): 1204-1214. PMID 30085898
6. Sandberg EM, Tummers FHMP, Cohen SL, et al. Reintervention risk and quality of life outcomes after uterine-sparing interventions for fibroids: a systematic review and meta-analysis. *Fertil Steril.* Apr 2018; 109(4): 698-707.e1. PMID 29653718
7. Havryliuk Y, Setton R, Carlow JJ, et al. Symptomatic Fibroid Management: Systematic Review of the Literature. *JSLs.* 2017; 21(3). PMID 28951653
8. Lin L, Ma H, Wang J, et al. Quality of Life, Adverse Events, and Reintervention Outcomes after Laparoscopic Radiofrequency Ablation for Symptomatic Uterine Fibroids: A Meta-Analysis. *J Minim Invasive Gynecol.* 2019; 26(3): 409-416. PMID 30253997
9. 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.* Dec 2019; 29(12): 1507-1517. PMID 31702440
10. Annreiter C, Oppelt P. A Systematic Review of the Treatment of Uterine Myomas Using Transcervical Ultrasound-Guided Radiofrequency Ablation with the Sonata System. *J Minim Invasive Gynecol.* Aug 2021; 28(8): 1462-1469. PMID 33892184
11. Zhang J, Go VA, Blanck JF, et al. A Systematic Review of Minimally Invasive Treatments for Uterine Fibroid-Related Bleeding. *ReprodSci.* Oct 2022; 29(10): 2786-2809. PMID 34480321
12. 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): 261-5. PMID 24698202

13. Rattray DD, Weins L, Regush LC, et al. 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. *Clinicoecon Outcomes Res.* 2018; 10: 201-212. PMID 29670382
14. Yu S, Silverberg K, Bhagavath B, et al. Post-Market Safety of Laparoscopic Ultrasound-Guided Radiofrequency Ablation. *JLS.* 2020;24(4). PMID 33510567
15. Yu S, Bhagavath B, Shobeiri SA, et al. Clinical and Patient Reported Outcomes of Pre- and Postsurgical Treatment of Symptomatic Uterine Leiomyomas: A 12-Month Follow-up Review of TRUST, a Surgical Randomized Clinical Trial Comparing Laparoscopic Radiofrequency Ablation and Myomectomy. *J Minim Invasive Gynecol.* Jun 2022; 29(6): 726-737. PMID 35085837
16. Hahn M, Brucker S, Kraemer D, et al. Radiofrequency Volumetric Thermal Ablation of Fibroids and Laparoscopic Myomectomy: Long-Term Follow-up From a Randomized Trial. *Geburtshilfe Frauenheilkd.* May 2015; 75(5): 442-449. PMID 26097247
17. Krämer B, Hahn M, Taran FA, et al. Interim analysis of a randomized controlled trial comparing laparoscopic radiofrequency volumetric thermal ablation of uterine fibroids with laparoscopic myomectomy. *Int J Gynaecol Obstet.* May 2016; 133(2): 206-11. PMID 26892690
18. Berman JM, Guido RS, Garza Leal JG, et al. Three-year outcome of the Halt trial: a prospective analysis of radiofrequency volumetric thermal ablation of myomas. *J Minim Invasive Gynecol.* 2014; 21(5): 767-74. PMID 24613404
19. Berman JM, Bradley L, Hawkins SM, et al. Uterine Fibroids in Black Women: A Race-Stratified Subgroup Analysis of Treatment Outcomes After Laparoscopic Radiofrequency Ablation. *J Womens Health (Larchmt).* Apr 2022; 31(4): 593-599. PMID 34287028
20. Jacoby VL, Parvataneni R, Oberman E, et al. Laparoscopic Radiofrequency Ablation of Uterine Leiomyomas: Clinical Outcomes during Early Adoption into Surgical Practice. *J Minim Invasive Gynecol.* 2020; 27(4): 915-925. PMID 31376584
21. Miller CE, Osman KM. Transcervical Radiofrequency Ablation of Symptomatic Uterine Fibroids: 2-Year Results of the SONATA Pivotal Trial. *J Gynecol Surg.* Dec 01 2019; 35(6): 345-349. PMID 32226268
22. Lukes A, Green MA. Three-Year Results of the SONATA Pivotal Trial of Transcervical Fibroid Ablation for Symptomatic Uterine Myomata. *J Gynecol Surg.* Oct 01 2020; 36(5): 228-233. PMID 33061253
23. 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. PMID 26918001
24. Shifrin G, Engelhardt M, Gee P, et al. Transcervical fibroid ablation with the Sonata™ system for treatment of submucous and large uterine fibroids. *Int J Gynaecol Obstet.* Oct 2021; 155(1): 79-85. PMID 33544889
25. Rhode Island General Law (RIGL) 27-18-44 (Accident and Sickness)
www.rilin.state.ri.us/Statutes/title27/27-18/index.htm
26. Rhode Island General Law (RIGL) 27-19-36.1 (Nonprofit Hospital Service Corporation)
www.rilin.state.ri.us/Statutes/TITLE27/27-19/27-19-36.htm
27. Rhode Island General Law (RIGL) 27-29-36.1 (Nonprofit Medical Service Corporation)
www.rilin.state.ri.us/Statutes/TITLE27/27-20/INDEX.htm
28. Rhode Island General Law (RIGL) 27-41-45.1 (Health Maintenance Organization).
www.rilin.state.ri.us/Statutes/TITLE27/27-41/INDEX.htm

i

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

