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

EFFECTIVE DATE: 09|01|2022
POLICY LAST UPDATED: 03|16|2022

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.

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

Surgery 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 transcutaneous 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 Acessa™ System (Acessa 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 Acessa™ 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 Accessa 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.

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)

RELATED POLICIES

Magnetic Resonance Imaging Guided Focused Ultrasound
Unlisted Procedures

PUBLISHED

Provider Update, May/August 2022
Provider Update, January 2022
Provider Update, November 2020
Provider Update, August 2019
Provider Update, November 2018

REFERENCES

1. Stewart MR, Adelman VL, Jacoby MR. Management of Symptomatic Uterine Leiomyomas: ACOG Practice Bulletin, Number 228. Obstet Gynecol. 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 North Am. 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 individuals: results of a national survey. J Individualss 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 Individuals with Uterine Fibroids. J Individualss 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. Jul-Sep 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. Mar 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. Arnreiter 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. 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
12. 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
13. Yu S, Silverberg K, Bhagavath B, et al. Post-Market Safety of Laparoscopic Ultrasound-Guided Radiofrequency Ablation. JSLS. Oct-Dec 2020; 24(4). PMID 33510567
14. 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
15. Kramer 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
16. 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. May 2020; 27(4): 915-925. PMID 31376584
17. 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
18. 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
19. Brolmann H, Bongers M, Garza-Leal JG, et al. The FAST-EU trial: 12-month clinical outcomes of individuals after intrauterine sonography-guided transcervical radiofrequency ablation of uterine fibroids. Gynecol Surg. NA 2016; 13: 27-35. PMID 26918001
20. 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
21. Christoffel L, Romer T, Schiermeier S. Transcervical Radiofrequency Ablation of Uterine Fibroids Global Registry (SAGE): Study Protocol and Preliminary Results. Med Devices (Auckl). 2021; 14: 77-84. PMID 33688276
22. Keltz J, Levie M, Chudnoff S. Pregnancy Outcomes After Direct Uterine Myoma Thermal Ablation: Review of the Literature. J Minim Invasive Gynecol. May 2017; 24(4): 538-545. PMID 28109894
23. Berman JM, Shashoua A, Olson C, et al. Case Series of Reproductive Outcomes after Laparoscopic Radiofrequency Ablation of Symptomatic Myomas. J Minim Invasive Gynecol. Mar 2020; 27(3): 639-645. PMID 31238151
24. Goldfarb HA. Bipolar laparoscopic needles for myoma coagulation. J Am Assoc Gynecol Laparosc. Feb 1995; 2(2): 175-9. PMID 9050553
25. Goldfarb HA. Nd:YAG laser laparoscopic coagulation of symptomatic myomas. J Reprod Med. Jul 1992; 37(7): 636-8. PMID 1387912
26. Nisolle M, Smets M, Malvaux V, et al. Laparoscopic myolysis with the Nd:YAG laser. J Gynecol Surg. 1993; 9(2): 95-9. PMID 10171973
27. Donnez J, Squifflet J, Polet R, et al. Laparoscopic myolysis. Hum Reprod Update. Nov-Dec 2000; 6(6): 609-13. PMID 11129695
28. Phillips DR, Nathanson HG, Milim SJ, et al. Laparoscopic Leiomyoma Coagulation. J Am Assoc Gynecol Laparosc. Aug 1996; 3(4, Supplement): S39. PMID 9074213
29. Zreik TG, Rutherford TJ, Palter SF, et al. Cryomyolysis, a new procedure for the conservative treatment of uterine fibroids. J Am Assoc Gynecol Laparosc. Feb 1998; 5(1): 33-8. PMID 9454874
30. Zupi E, Piredda A, Marconi D, et al. Directed laparoscopic cryomyolysis: a possible alternative to myomectomy and/or hysterectomy for symptomatic leiomyomas. Am J Obstet Gynecol. Mar 2004; 190(3): 639-43. PMID 15041993
31. Zupi E, Marconi D, Sbracia M, et al. Directed laparoscopic cryomyolysis for symptomatic leiomyomata: one-year follow up. J Minim Invasive Gynecol. Jul-Aug 2005; 12(4): 343-6. PMID 16036195
32. Hindley JT, Law PA, Hickey M, et al. Clinical outcomes following percutaneous magnetic resonance image guided laser ablation of symptomatic uterine fibroids. Hum Reprod. Oct 2002; 17(10): 2737-41. PMID 12351555
33. 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 January 3, 2022.

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS