Clinical Policy: Radiofrequency Ablation of Uterine Fibroids

Reference Number: LA.CP.MP.187 Coding Implications
Date of Last Revision: 5/21 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Uterine leiomyomas are the most common solid pelvic tumors in women and the leading indication for hysterectomy. Many women seek an alternative to hysterectomy because they desire future childbearing or wish to retain their uteri. As alternatives to hysterectomy become increasingly available, it is important to understand the efficacies and risks of these treatments.[1] This policy describes medical necessity criteria for radiofrequency ablation of uterine fibroids.

Policy/Criteria
I. It is the policy of Louisiana Healthcare Connections that *radiofrequency ablation and the use of the Acessa™ and Sonata® Systems* is considered experimental/investigational for the treatment of uterine fibroids due to a lack of established efficacy.

Background
According to the American College of Obstetricians and Gynecologists, uterine fibroids, also called leiomyomas or myomas, are benign growths that develop from the muscle tissue of the uterus. These growths can vary greatly in size, shape, and location. Uterine fibroids occur most commonly in women aged 30–40 years, although they can occur at any age. They are more common in African American women than in white women. Uterine fibroids are typically detected during a routine pelvic exam.[1]

Common symptoms of fibroids include changes in menstruation, cramping, bleeding at times other than during menstruation, pain in the abdomen or lower back and pain during sex. Women may also experience difficult or frequent urination or constipation and painful bowel movements. Fibroids can call cause an enlarged uterus and abdomen and lead to miscarriages or infertility.[1]

There are several non-surgical treatments for uterine fibroids including medication such as birth control, gonadotropin-releasing hormone agonists and progestin. Surgical options include myomectomy, the surgical removal of fibroids while leaving the uterus in place, and hysterectomy in more severe cases.[1]

Recently, radiofrequency ablation has been introduced as a treatment for uterine fibroids.

The Acessa™ Procedure is a minimally invasive, uterine sparing, outpatient treatment for fibroids found within the uterine wall. Using radiofrequency ablation to destroy each fibroid by applying controlled energy through a small needle, the Acessa™ Procedure does not affect surrounding tissues and multiple fibroids can be treated though a single laparoscopic uterine puncture. Additionally, the generator also performs electrocautery to stop bleeding. The body ultimately reabsorbs the destroyed tissue following this procedure.[2,3]

The Sonata® System combines real-time intrauterine ultrasound guidance with targeted radiofrequency ablation in an incisionless procedure to treat symptomatic uterine fibroids. The

system also includes a graphical guidance software that provides the operating gynecologist with real-time graphic overlay on the live ultrasound image.[3,4]

The Hayes Technology Assessment for radiofrequency ablation of uterine fibroids states that the body of evidence assessing Sonata sonography-guided transcervical fibroid ablation is of low quality, and that comparative effectiveness evidence comparing radiofrequency ablation with alternative uterine sparing fibroid treatments is insufficient to draw conclusions. In general, statistically significant differences were not noted in most outcomes; however, comparative analyses were limited to 1 to 2 randomized controlled trials and were not always conducted statistically.[2]

Coding Implications

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CPT Codes	Description
58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency

HCPCS Codes	Description
0404T	Trans cervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Converted corporate to local policy.	08/15/2020	
"Experimental/investigational" verbiage replaced in policy statement with descriptive language. References reviewed and updated.	5/2021	

References

1. Alternatives to Hysterectomy in the Management of Leiomyomas. Practice Bulletin Number 96 (Replaces Practice Bulletin Number 16, May 2000 and Committee Opinion Number 293, February 2004. Reaffirmed 2019) The American College of Obstetricians and Gynecologists. www.acog.org. Published August 2008. Accessed April 7, 2021.
2. Uterine fibroids. Frequently asked questions: Gynecologic Problems. The American College of Obstetricians and Gynecologist. www.acog.org. Accessed March 17, 2021.

3. Laparoscopic radiofrequency volumetric thermal ablation (Acessa System; Halt Medical Inc.) for treatment of uterine fibroids. Hayes website www.hayesinc.com. Published December 20, 2019. Accessed March 17, 2021.
4. Acessa™ System. Halt Medical, Inc. Web site. http://www.acessaprocedure.com/healthcare-professionals/. Accessed March 17, 2021.
5. Transcervical radiofrequency ablation with the Sonata System for symptomatic uterine fibroids. Hayes website www.hayesinc.com. Published September 30, 2020. Accessed April 7, 2021.
6. Sonata® Treatment. Gynesoncis, Inc. Website https://sonatatreatment.com/for-physicians/the-sonata-system/. Accessed April 2, 2020.
7. Stewart, EA. Overview of treatment of uterine leiomyomas (fibroids). In: UpToDate. Barbieri RL and Chakrabarti A, Eds. Published January 4, 2021. Accessed March 17, 2021.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.