Clinical Policy: Radiofrequency Ablation of Uterine Fibroids

Reference Number: WNC.CP.154 Coding Implications
Last Review Date: 11/22 Revision Log

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

Note: When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Description

This policy describes the medical necessity criteria for radiofrequency ablation (RFA) of uterine fibroids.

Policy/Criteria

I. It is the policy of WellCare of North Carolina® that there is insufficient high quality evidence in the peer reviewed medical literature to determine the safety and efficacy for radiofrequency ablation of uterine fibroids utilizing the Acessa™ or Sonata® Systems.

Background

According to the American College of Obstetricians and Gynecologists (ACOG), uterine fibroids (UF), 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 are common and estimated to affect 70% of white women and 80% of black women by age 50 years. They are typically detected during a routine pelvic exam.[1,2]

Although many women with UFs are asymptomatic, common symptoms include changes in menstruation, cramping, bleeding at times other than during menstruation, pelvic pressure, 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 cause an enlarged uterus and abdomen and lead to miscarriages or infertility.[1,7]
Non-surgical treatment for uterine fibroids includes pharmaceutical options such as hormonal contraceptives, nonsteroidal anti-inflammatory drugs, gonadotropin-releasing hormone agonists, progesterone modulators and aromatase inhibitors. Surgical options include myomectomy, the surgical removal of fibroids (which spares the uterus) and hysterectomy, which is the definitive treatment, eliminating the possibility of recurrence.[1,7] Myomectomy may be performed abdominally, laparoscopically or hysteroscopically depending on the size, number and location of the fibroids.[1,2]

Recently, radiofrequency ablation has been introduced as an alternative treatment for uterine fibroids. Currently there are two systems for RFA, the Acessa™ system and the Sonata® system.

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

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puncture. Additionally, the generator also performs electrocautery to stop bleeding. The body ultimately reabsorbs the destroyed tissue following this procedure[2,3]
Regarding the Acessa procedure, Hayes states, in general, a low-quality body of evidence derived from 6 studies (published in 11 articles) suggests that radiofrequency volumetric thermal ablation (RFVTA) may result in improved symptoms and some improvements in general quality of life assessments from baseline. Comparative effectiveness evidence comparing RFVTA 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 one to two randomized controlled trials and were not always conducted statistically. No studies evaluated success in achieving pregnancy among women attempting to conceive after RFVTA. Three studies limited the eligible patient populations to women who had no desire to maintain fertility. Furthermore, the efficacy of RFVTA for fibroids of varying International Federation of Gynecology and Obstetrics classification was evaluated by only one study. Large, well-controlled trials comparing RFVTA with other minimally invasive, uterinesparing procedures are needed, especially evaluating the safety and effectiveness of RFVTA among women wishing to maintain fertility.[2]

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.[4,5]

Regarding the Sonata procedure, Hayes states, a very-low-quality body of evidence is insufficient to draw conclusions regarding the efficacy and safety of transcervical RFA for symptomatic UF. Compared with pretreatment status, the Sonata procedure was associated with statistically significant improvements in symptoms, quality of life, and fibroid volume. Due to the limited number of studies, consistency of results cannot be determined. Additional studies comparing the Sonata procedure with established treatments for UF are needed to determine whether the Sonata procedure provides meaningful clinical benefits relative to currently available options. All 3 studies excluded women with an intent for future fertility; however, 2 studies reported that 1 woman in each study conceived, carried to term, and delivered infants.[4]

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2021, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

+ Indicates a code(s) requiring an additional character

ICD-10-CM Code	Description
No applicable codes.	

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original approval date	03/21	06/21
Updated background and references.	02/22	05/22
Annual review. References reviewed and updated.	11/22	

References

1. The American College of Obstetricians and Gynecologists. Frequently asked questions: Uterine Fibroids. https://www.acog.org/womens-health/faqs/uterine-fibroids. Published December 2018. Accessed February 8, 2022.
2. Laparoscopic radiofrequency volumetric thermal ablation (Acessa System; Halt Medical Inc.) for treatment of uterine fibroids. Hayes www.hayesinc.com. Published December 20, 2019 (annual review March 4, 2021). Accessed February 8, 2022.
3. Acessa Product Page. https://gynsurgicalsolutions.com/patients/treatment-options/acessa/procedure-steps-and-components/ February 8, 2022.
4. Transcervical radiofrequency ablation with the Sonata System for symptomatic uterine fibroids. Hayes www.hayesinc.com. Published September 30, 2020. Accessed February 8, 2022.
5. Sonata® Treatment. Gynesoncis, Inc. https://sonatatreatment.com/for-physicians/the-sonata-system/. Accessed February 8, 2022.
6. Stewart, EA. Uterine fibroids (leiomyomas): Treatment overview. UpToDate. www.uptodate.com.. Published August 6, 2021. Accessed February 8, 2022.
7. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins–Gynecology. Management of Symptomatic Uterine Leiomyomas: ACOG Practice Bulletin, Number 228. Obstet Gynecol. 2021;137(6):e100-e115. doi:10.1097/AOG.0000000000004401

North Carolina Guidance

Eligibility Requirements

a. An eligible beneficiary shall be enrolled in either:
   1. the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise); or
   2. the NC Health Choice (NCHC is NC Health Choice program, unless context clearly indicates otherwise) Program on the date of service and shall meet the criteria in this policy.

b. Provider(s) shall verify each Medicaid or NCHC beneficiary's eligibility each time a service is rendered.

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c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.
d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.

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2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below:
   NCTracks Provider Claims and Billing Assistance Guide:
   https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html
   EPSDT provider page: https://medicaid.ncdhhs.gov/

EPSDT does not apply to NCHC beneficiaries.

Provider(s) Eligible to Bill for the Procedure, Product, or Service
To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid or NCHC qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

Compliance
Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

Claims-Related Information
Provider(s) shall comply with the, NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

a. Claim Type - as applicable to the service provided:
   Professional (CMS-1500/837P transaction)
   Institutional (UB-04/837I transaction)
   Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
b. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) - Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.
c. Code(s) - Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer

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to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service

d. Modifiers - Providers shall follow applicable modifier guidelines.
e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
f. Co-payments -
   For Medicaid refer to Medicaid State Plan:
   https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan
   For NCHC refer to NCHC State Plan:
   https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan
g. Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/.

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. The Health Plan 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. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

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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. The Health Plan 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/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees 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 the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

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