

Clinical Policy: Endometrial Ablation

Reference Number: WNC.CP.120 Last Review Date: 05/24 Coding Implications Revision Log

See <u>Important Reminder</u> 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 guidelines for an endometrial ablation. Endometrial ablation is a minimally invasive surgical procedure used to treat premenopausal abnormal uterine bleeding.^{2,12,21}, Although this procedure preserves the uterus, endometrial ablation is indicated for those who have no desire for future fertility.¹¹ The two major classifications of endometrial ablation procedures are first generation resectoscopic techniques and second generation nonresectoscopic methods. Quality of life resulting from reduced bleeding and amenorrhea, may improve following endometrial ablation procedures.

Policy/Criteria

- I. It is the policy of WellCare of North Carolina[®] that Endometrial Ablation using an FDA approved device, is medically necessary when **all** the following criteria are met:
 - A. One of the following indications:
 - 1. Menorrhagia unresponsive to at least 3 months of hormonal or medical therapy (unless contraindicated to such therapy); ²⁵
 - 2. Abnormal uterine bleeding, including residual menstrual bleeding after at least 6 months of androgen therapy in a member/enrollee with a female reproductive system undergoing treatment for gender affirmation;²³
 - **B.** Cervical cytology or HPV testing and gynecological exam excludes significant cervical disease;²⁵
 - C. Endometrial sampling prior to the procedure has excluded malignancy or hyperplasia;²⁵
 - **D.** No structural anomalies, such as fibroids or polyps that require transmural surgery or represent a contraindication to an ablation procedure
 - **E.** If anatomic or pathologic conditions exist that may result in a weakened myometrium, only a resectoscopic endometrial ablation is appropriate;⁸¹
 - F. Thyroid disorders have been treated or ruled out.
 - G. Does NOT have any of the following contraindications:
 - 1. Premenopausal with future desire for fertility;
 - 2. Untreated disorders of hemostasis;⁸¹
 - 3. Pregnancy at time of procedure;
 - 4. Intrauterine device at time of procedure;
 - 5. Active pelvic infection.
- **II.** It is the policy of WellCare of North Carolina[®] that there is insufficient scientific evidence to support effectiveness for the following:





- A. Photodynamic endometrial ablation procedures;
- **B.** Endometrial ablation for the treatment of all other conditions than those specified above.

Background

Menstrual disorders are among the most prevalent gynecological health problems in the United States, and abnormal menstrual bleeding affects up to 30% of people at some time during their reproductive years.⁴

Traditionally, medication therapy has been the initial treatment of choice, followed by hysterectomy, when medication does not provide the desired outcome. The levonorgestrel releasing intrauterine device (e.g., Mirena or Liletta; referred to as LNG 52 mg IUD) is an option in patients who do not desire pregnancy. Both the LNG 52 mg IUD and endometrial ablation are effective in reducing menstrual blood loss. The decision to use the LNG 52 mg or endometrial ablation depends on a patient's preferences regarding treatment factors, such as plans for fertility and contraception, convenience, and risks of anesthesia.^{21,24,29} Endometrial ablation can offer an alternative to the more invasive hysterectomy treatment option.⁹

Endometrial ablation can also be used to treat residual menstrual bleeding in transgender men.²³ Generally, masculinizing hormones cause cessation of menses within 2-6 months of initiation. The addition of a progestational agent or endometrial ablation may be considered for those wishing to completely cease menses.¹⁷

Endometrial ablation encompasses several techniques of targeted destruction of the endothelial surface of the uterine cavity through a vast array of energy sources. While hysterectomies provide permanent relief from abnormal uterine bleeding, they are associated with longer recovery times, higher rates of postoperative complications, substantial convalescent time and morbidity.8,⁹ Although endometrial ablation has a high success rate, there are specific cases of endometrial ablation failures in which the patient will return for repeat care, often for a hysterectomy.⁹⁰ The effectiveness of endometrial ablation was demonstrated in a report of 26 patients who underwent ablation. After one year, 25 of the 26 patients reported reduced bleeding with no further medical or surgical interventions; one patient required a hysterectomy due to persistent uterine bleeding related to a leiomyoma.³⁰ Among patients who return for hysterectomy after failure of endometrial ablation, adenomyosis, leiomyomata and endometriosis are the most common contributing diagnoses.^{20,31}

Pregnancy following endometrial ablation can occur, and premenopausal patients should be counseled that an appropriate contraception method should be used. Endometrial ablation is predominately indicated for patients who have no desire for future fertility.²⁰ Post-operative complications from endometrial ablation include: (1) pregnancy after endometrial ablation; (2) pain-related to obstructed menses (hematometra, post ablation tubal sterilization syndrome); (3) failure to control menses; (4) risk from preexisting conditions (endometrial neoplasia, cesarean section; and (5) infection.^{13,21} Uterine perforation has been reported in 0.3 percent of nonresectoscopic endometrial ablation procedures and 1.3 percent of resectoscopic ablations or resections.²¹



Table 1: FDA-Approved Techniques Approved For Endometrial Ablation				
Procedure ^{1,2,3}	System ^{1,2,13}	Device Size ¹ (mm)	Treatmen t Time ^{1,} ¹³ (min)	Amenorrhe a Rate ²
Resectoscopic Ablation				
Laser Vaporization				37%
Electrosurgical Rollerball				25 to 60%
Transcervical resection of				26 to40%
endometrium				
Radiofrequency Vaporization				N/A
Non-Resectoscopic Ablation				
Cryotherapy	Cerene	4.5	10 to 8	53%
Heated Free Fluid	Hydro	7.8	\sim 14 *	71%
	ThermAblator			
Vapor ablation	Mara		2.0	
Radiofrequency Electricity	NovaSure	7.2	1.5	41%
Combined thermal and bipolar radiofrequency ablation device	Minerva		2.0	

3 minutes to heat the fluid to 90°C, 10 minutes to maintain that temperature to ablate the endometrium, and approximately 1 minute for the fluid to cool down allowing the device to be removed.

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 2024, 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
58353	Endometrial ablation, thermal, without hysteroscopic guidance
58356	Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed
58563	Hysteroscopy, surgical; with endometrial ablation (e.g., endometrial resection, electrosurgical ablation, thermoablation)



ICD-10-CM Diagnosis Codes that Support Coverage Criteria

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ICD-10-CM Code	Description
N92.0	Excessive and frequent menstruation with regular cycle
N92.1	Excessive and frequent menstruation with irregular cycle
N92.4	Excessive bleeding in the premenopausal period
N92.5	Other specified irregular menstruation
N92.6	Irregular menstruation, unspecified
N93.8	Other specified abnormal uterine and vaginal bleeding
N93.9	Abnormal uterine and vaginal bleeding, unspecified

Reviews, Revisions, and Approvals	Reviewed	Approval
	Date	Date
Original Approval date.	02/21	05/21
Added "HPV testing" to Section I.B. Updated investigational verbiage in	04/22	05/22
Section II. Revised Table 1 to add ThermaChoice. References reviewed and		
updated.		
Annual Review. Criteria I.A.2, reworded portion pertaining to abnormal	05/23	05/23
bleeding in transgender members from "female to male transgender person" to		
"member/enrollee with a female reproductive system undergoing treatment for		
gender affirmation." Changed Criteria I.D. from "no structural anomalies, such		
as fibroids or polyps that require surgery or represent a contraindication to an		
ablation procedure, or previous transmyometrial uterine surgery (including		
classical cesarean)" to "no structural anomalies, such as fibroids or polyps that		
require transmural surgery or represent a contraindication to an ablation		
procedure." Added contraindication criteria I.F.6. "Previous classical cesarean		
or other transmural surgery." Added to Background w/no change to criteria		
"Traditionally, medication therapy has been the initial treatment of choice,		
followed by hysterectomy, when medication does not provide the desired		
outcome. The levonorgestrel (LNG)-releasing intrauterine device (e.g., Mirena		
or Liletta; referred to as LNG 52) is an option in patients who do not desire		
pregnancy. Both the LNG 52 IUD and endometrial ablation are effective in		
reducing menstrual blood loss. The decision to use the LNG 52 or endometrial		
ablation depends on a patient's preferences regarding treatment factors, such as		
plans for fertility and contraception, convenience, and risks of anesthesia. ^{22,25}		
Endometrial ablation can offer an alternative to the more invasive		
hysterectomy treatment option. ¹⁰ NCHC verbiage removed from NC Guidance		
Verbiage. Added requirement in I.F. that thyroid disorders have been treated or		
ruled out. Removed contraindication "previous classic cesarean or other		
transmural surgery" from I.G. Background and Table 1 updated. Added		
requirement in I.F. that thyroid disorders have been treated or ruled out.		
Removed contraindication "previous classic cesarean or other transmural		
surgery" from I.G. Background and Table 1 updated. Minor rewording with no		
clinical significance. References reviewed and updated.		



Annual Review. Under Description, added verbiage "resulting from reduced	05/24	05/24
bleeding and amenorrhea," Under Criteria I. added "using an FDA approved		
device," Under Background, paragraph 3, added "adenomyosis, leiomyomata		
and" Removed HCPCS table.		

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North Carolina Guidance

Eligibility Requirements

- a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
- b. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
- c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

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.
- 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/

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 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:

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 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
- g. Reimbursement Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: <u>https://medicaid.ncdhhs.gov/</u>.

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 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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