## NC Medicaid Sterilization Procedures

## Medicaid and Health Choice Clinical Coverage Policy No: 1E-3 Amended Date:

### DRAFT

## To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

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## NC Medicaid Sterilization Procedures

### Medicaid and Health Choice Clinical Coverage Policy No: 1E-3 Amended Date:

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#### **Related Clinical Coverage Policies**

Refer to <u>https://medicaid.ncdhhs.gov/</u> for the related coverage policies listed below:

1E-7, Family Planning Services

1L-1, Anesthesia Services

<u>1E-1, Hysterectomy</u>

1S-5 Genetic Testing for Susceptibility to Breast and Ovarian Cancer (BRCA)

## **1.0** Description of the Procedure, Product, or Service

Sterilization is a permanent method of birth control. Sterilization procedures for women are called tubal occlusion. The procedure for men is called vasectomy. Sterilization means any medical procedure, treatment or operation for the sole purpose of rendering an individual permanently incapable of reproducing and not related to the repair of a damaged or dysfunctional body part.

#### 1.1 Definitions

#### 1.1.1 Tubal Sterilization Procedure

Female sterilization, also called tubal occlusion or ligation, is a permanent contraceptive method for women beneficiaries who do not want more children to become pregnant. The method requires a simple surgical procedure that prevents the egg from passing down the fallopian tubes into the uterus. A physician can block the fallopian tubes several different ways. They can be clipped closed with bands or rings. They can be cut and tied closed, or they can be cauterized with an electric needle. Once the fallopian tubes are cauterized, scar tissue forms, which blocks them. A surgical cut must be made in either the abdomen just above the public hair, in the belly button and lower abdomen, or in the back wall of the vagina. The procedure can be done using a local anesthetic to numb the area, or a general anesthetic. The two most common female sterilization approaches are minilaparotomy, which is usually performed under local anesthesia with light sedation, and laparoscopy, which requires general anesthesia.

#### 1.1.2 Prophylactic Opportunistic Bilateral Salpingectomy

Female sterilization can also be performed by removal of both fallopian tubes. Studies suggest that total removal of the tubes could result in a lower risk of developing ovarian cancer.

Opportunistic bilateral salpingectomy is the surgical removal of the fallopian tubes so the risk of ovarian cancer is reduced. This procedure can be performed independently or in conjunction with another abdominal surgery, such as a hysterectomy

#### 1.1.3 Vasectomy

Vasectomy is an operation designed to make a male sterile by making small incisions in the skin of the scrotum, with a local anesthetic. The vas deferens is severed and the scrotal incision closed. The entire procedure is repeated on the opposite side.

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A vasectomy is the surgical division or resection of all or part of the vas deferens to induce sterility

### 1.1.4 Preterm Delivery

Preterm delivery is a delivery that occurs at less than 37 weeks gestation.

#### 2.0 Eligibility Requirements

- 2.1 Provisions
  - 2.1.1 General

# (The term "General" found throughout this policy applies to all Medicaid and NCHC policies)

- 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 **Section 3.0 of this policy**.
- b. Provider(s) shall verify each Medicaid or NCHC 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.
- 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.

#### 2.1.2 Specific

#### <u>Medicaid</u>

Medicaid shall cover sterilization procedures for both men and women beneficiaries age 21 and over that meet requirements found in 42 CFR Part 441, Subpart F – Sterilization and this clinical coverage policy.

#### <u>NCHC</u>

NCHC <u>beneficiaries are not eligible for</u> shall not cover Sterilization Procedures.

#### 2.2 Special Provisions

#### 2.2.1 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 clinician).

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.

#### b. 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/providermanuals.html

EPSDT provider page: https://medicaid.ncdhhs.gov/

#### 2.2.2 EPSDT does not apply to NCHC beneficiaries

# **2.2.3** Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for a NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for a NCHC beneficiary.

#### 2.3 Undocumented Aliens

Undocumented aliens are eligible for Medicaid emergency services only. Sterilization procedures are not considered an emergency service. Undocumented aliens are not eligible for sterilization procedures.

## 3.0 When the Procedure, Product, or Service Is Covered

*Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.* 

#### 3.1 General Criteria Covered

Medicaid shall cover procedures, products, and services related to this policy when they are medically necessary, and:

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

#### **3.2** Specific Criteria Covered

# **3.2.1** Specific criteria covered by both Medicaid and NCHC None Apply.

#### 3.2.2 Medicaid Additional Criteria Covered

- A. Medicaid shall cover voluntary sterilization procedures tubal sterilization procedure or vasectomy for a beneficiary beneficiaries that meets all of the following criteria: requirements found in 42 CFR Part 441, Subpart F Sterilization and this clinical coverage policy. Including, a beneficiary who:
  - 1. is at least 21 years of age at time of the informed consent is signed;
  - 2. is not legally declared to be mentally incompetent;
  - 3. is not one of following:
    - i. involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental hospital or other facility of the care and treatment of mental illness; or
    - ii. confined, under a voluntary commitment in a mental hospital or other facility for the care and treatment of mental illness in a corrective, penal, or mental rehabilitation facility; and
  - 4. gave informed consent.
- B. <u>Medicaid shall cover opportunistic bilateral salpingectomy when the</u> <u>beneficiary meets all of the requirements listed in section 3.2.2 (A) and has</u> <u>tested positive for BRCA1 or BRCA2</u>

#### 3.2.3 NCHC Additional Criteria Covered

None Apply.

#### 4.0 When the Procedure, Product, or Service Is Not Covered

*Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.* 

There is no EPSDT exception to the following requirements. The Code of Federal Regulations (CFR) at 42 Sec. 441.253 states that federal financial participation is available in expenditures for the sterilization of a beneficiary only if the beneficiary is at least 21 years old at the time consent is obtained.

#### 4.1 General Criteria Not Covered

Medicaid shall not cover procedures, products, and services related to this policy when:

- a. the beneficiary does not meet the eligibility requirements listed in Section 2.0;
- b. the beneficiary does not meet the criteria listed in Section 3.0;
- c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

#### 4.2 Specific Criteria Not Covered

**4.2.1** Specific Criteria Not Covered by both Medicaid and NCHC None Apply.

#### 4.2.2 Medicaid Additional Criteria Not Covered

Medicaid shall not cover sterilization when:

- a. the federal guidelines listed in 42 CFR Part 441, Subpart F Sterilization have not been met;
- b. the beneficiary is mentally incompetent, as defined under 42 CFR 441.251;
- the beneficiary is an institutionalized individual, as defined under 42 CFR 441.251; and
- a. <u>the requirements listed in section 3.2.2 have not been met.</u>
- b. -for\_permanent birth control system by bilateral occlusion of the fallopian tubes or hysteroscopic tubal sterilization/transcervical sterilization (Essure).
- **Note**: If a judicial court orders a sterilization procedure for a Medicaid beneficiary who is a ward of the county and mentally incompetent, the beneficiary is not eligible for sterilization procedures.

Note: Bayer (manufacturer) discontinued sales and distribution of Essure System.

#### 4.2.3 Sterilization Reversals

Medicaid shall not cover procedures for the reversal of sterilization. Sterilization reversal procedures are include reverse bilateral fallopian tube trans-section by

means of bilateral salpingoplasty and reversal of a bilateral vasectomy by means of a bilateral vasovasostomy.

#### 4.2.4 NCHC Additional Criteria Not Covered

- a. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
  - 1. No services for long-term care.
  - 2. No nonemergency medical transportation.
  - 3. No EPSDT.
  - 4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

## 5.0 Requirements for and Limitations on Coverage

*Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.* 

#### 5.1 **Prior Approval**

Medicaid shall not require prior approval for Sterilization Procedures.

#### 5.2 **Prior Approval Requirements**

5.2.1 General

None apply.

5.2.2 Specific

None Apply.

#### 5.3 Sterilization Consent

Consent is required for all voluntary sterilizations including prophylactic bilateral salpingectomy. The beneficiary shall provide voluntary informed consent according to the requirement found in this Medicaid policy and the federal regulations listed in 42 CFR 441.253, 42 CFR 441.257 and 42 CFR 441.258.

#### 5.3.1 Date of Consent

Consent must be obtained at least 30, but not more than 180, consecutive days prior to the date of the sterilization, except under the following circumstances:

- a. **Premature** <u>Preterm</u> Delivery: Informed consent must have been given at least 30 consecutive days before the expected date of delivery (EDD), and at least 72 hours must have passed since the informed consent was given.
- b. Emergency Abdominal Surgery: At least 72 hours must have passed since the informed consent was given.

#### 5.3.2 Obtaining <u>Informed</u> Consent

Informed consent for sterilization may not be obtained while the beneficiary to be sterilized is:

- a. in labor or childbirth;
- b. seeking to obtain or obtaining an abortion; or
- c. under the influence of alcohol or other substances that affect the beneficiary's state of awareness.
- d. <u>Under anesthesia or any other substance that affects the beneficiary's ability</u> to provide informed consent.

**Note**: Any state or local requirements for obtaining consent, except those requiring spousal consent, must be followed.

#### 5.3.3 Date of Confinement Expected Date of Delivery

The EDD must be documented on the sterilization consent form in cases of premature preterm delivery.

#### 5.3.3 Consent Form

Providers shall ensure that a valid sterilization consent form has been completed prior to rendering a sterilization procedure. The sterilization consent form is a federally mandated document and must be completed according to the instructions listed in **Attachment B**, Instructions for Completing the Consent <u>for Sterilization</u> Form.

Refer to Attachment C for a sample of the sterilization consent form.

- a. A new consent form cannot be initiated after the sterilization procedure or after the consent form has been submitted to the Department of Health and Human Services (DHHS) fiscal contractor.
- b. An existing consent form already on file at DHHS fiscal contractor may be modified to correct an error made on the consent form **unless the error occurred in one of the following areas**:
  - 1. Beneficiary handwritten signature;
  - 2. Date the consent form was signed by the beneficiary;
  - 3. Interpreter's handwritten signature;
  - 4. Date the consent form was signed by the interpreter;
  - 5. Handwritten signature of the person obtaining the consent (witness signature); or
  - 6. Date the consent form was signed by the person obtaining the consent (witness).
- c. If an error occurs during the inception of the consent form in any field noted above, the form must be voided, and a new consent form initiated.
- d. If an error occurs on the consent form, other than the areas noted in **Subsection 5.3.4 (b)**, providers shall:
  - 1. Strikethrough the error once on the original copy of the consent and make the correction.
  - 2. Do not use white-out or erase the error for correction purposes.

- 3. Send <u>a copy of</u> the corrected consent to DHHS fiscal contractor at the address located in **Attachment B Section C (2)**.
- e. The provider obtaining consent shall maintain the original completed sterilization consent form in the beneficiary's health record. A copy of this consent form must be provided to the beneficiary. Copies must be provided to the physician or provider conducting the procedure, the interpreter (if one is being used), and any other state agency or program requiring this documentation. A copy must be retained at the service site where the consent is being obtained.
- f. Providers shall add a valid National Provider Identifier (NPI) of the physician performing the procedure to the top left margin of the sterilization consent form. The beneficiary identification number must be added to the top right margin of the sterilization consent form, for the form to be processed. The facility NPI in which the procedure was performed must be added to the top center of the sterilization consent form.
- g. A valid sterilization consent must be on file with DHHS fiscal contractor before payment can be made for a sterilization procedure.
- <u>A Consent for Sterilization Form is not required when a beneficiary tests</u> <u>positive for BRCA1 or BRCA2 and requires a risk-reduction salpingo-</u> <u>oophorectomy</u>

#### 5.3.5 Signatures

The beneficiary to be sterilized and the person obtaining the beneficiary's consent shall sign and date the sterilization consent form. The signatures must be handwritten.

The physician's handwritten signature must be dated on or after the date of service (procedure date).

All handwritten signatures must be legible, or the <u>full (first and last)</u> name must be printed below the handwritten signature. Printed handwritten signatures are acceptable for the beneficiary, interpreter, witness, and physician.

The following types of signatures are **not** accepted:

- a. A changed, altered, revised, or modified signature. This includes erasures or use of correction fluid or correction tape on the signature.
- b. A traced signature. This is a copy of an original signature, produced by following its lines with a pen or pencil through a transparent medium.
- c. Use of a digital signature or signature stamp in lieu of an actual beneficiary, witness, interpreter, or physician signature on the sterilization consent form.
- d. Use of initials and abbreviations **are not** acceptable for the first name of the beneficiary, interpreter, witness, or physician.
- e. Signature of another physician on the consent instead of the physician who performed the procedure.

#### 5.4 Interpreter Services

When telephone interpreter services are needed to complete the sterilization consent form for non-English-speaking Medicaid beneficiaries, the interpreter's handwritten signature,

date of the interpreter's service, and the language used must be documented on the sterilization consent form Consent for Sterilization Form. In lieu of getting the interpreter's signature on the sterilization consent form at the time the service is provided, the interpreter who explains the procedure by telephone may fax or mail the attestation of interpreter services to the provider. Criteria for the faxed or mailed attestation are as follows:

- a. The wording of the attestation must be taken directly from the sterilization consent form.
- b. The interpreter shall write his or her signature and the date the interpreter services were rendered on the attestation form.
- c. The dates with the signatures of the beneficiary, interpreter, and person obtaining consent must all be the same.
- d. The attestation form must <u>contain</u> include the beneficiary's name, as it appears on the Medicaid identification card, as well as the beneficiary identification number.
- e. A copy of the attestation must be attached to the consent form when the provider submits the statement to DHHS fiscal contractor.
- f. The provider shall maintain the original attestation document with the consent form in the beneficiary's health record.

#### 5.5 Name Change Statement

A signed name change statement must be provided to DHHS fiscal contractor when the beneficiary's name listed on the claim is different than the name on the sterilization consent form. The name change statement must verify that the names are for the same person. This statement must be written on the provider's office letterhead. (Refer to **Attachment B (E)**, regarding name change statement).

#### 5.6 Limitations

This service places reasonable unit limitations on procedures and services. When extenuating circumstances require a provider to exceed a unit limitation, the denied claim and health records must be submitted as an adjustment for reconsideration. The following sterilization limitations apply:

- a. Sterilization procedures are covered for a beneficiary once in a lifetime unless documentation supports repeat due to failed procedure.
- b. Medicaid allows 100 percent reimbursement of the allowable amount on the fee schedule <u>or established OMB rate</u> for a sterilization and vaginal delivery or sterilization and cesarean section when they are the only surgery procedures performed on the same date of service.
- c. Dilation and curettage performed on the same date of service as a sterilization procedure is will be suspended for medical review. H and h ealth records may can be requested.

#### 6.0 **Provider(s)** Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services 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.

## 6.1 **Provider Qualifications and Occupational Licensing Entity Regulations**

None Apply.

#### 6.2 **Provider Certifications**

None Apply.

### 7.0 Additional Requirements

## *Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.*

#### 7.1 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).

## 8.0 Policy Implementation and History

Original Effective Date: January 1, 1974

#### History:

Date	Section Revised	Change
07/01/2008	Subsections 1.2,	Coverage of the Essure System procedure (effective with
	4.1.1, 3.2, 4.2, and	N.C. Medicaid approval date, September 1, 2003) and the
	Attachment A	hysterosalpingogram procedure (effective with N.C.
		Medicaid approval date, December 1, 2003) was added to
		the policy.
03/12/2012	all sections and	Technical changes to merge Medicaid and NCHC current
	attachment(s)	coverage into one policy.
07/01/2013	Section 5.3.4	Added information regarding consent form changes.
07/01/2013	Section 5.3.5	Added information regarding acceptable signatures,
		signature stamps usage, and use of initials
07/01/2013	Section 5.4	Changed wording from "should" to "must" in (a)
07/01/2013	Attachment B	Changes made in #'s 7, 11, 15, and 23 regarding the use of
		initials and signature stamps
07/01/2013	Attachment C	Added new consent form approved by CMS
07/01/2013	All sections and	Replaced "recipient" with "beneficiary."
	attachment(s)	
10/01/2015	All sections and	Updated policy template language and added ICD-10
	Attachments	codes to comply with federally mandated 10/1/2015
		implementation where applicable.
06/01/2017	All Sections	Updated CFR 441.250 through 259 to 42 CFR Part 441,
		Subpart F - Sterilization
06/01/2017	All Sections	Changed DMA fiscal agent to DHHS fiscal contractor.
06/01/2017	All Sections	Replaced "recipient" with "beneficiary."
06/01/2017	All Sections	Changed medical record to health record.
06/01/2017	Section 4.2.2	Clarified definition of mentally incompetent individual
		and institutionalized individual.
06/01/2017	Section 5.2	Updated 5.2.1 and 5.2.2. PA is not a requirement for a
		sterilization procedure.
06/01/2017	Section 5.3, 5.3.1,	Added 42 CFR 441.253 and deleted language found in
	5.3.2	CFR(s) in sections 5.3.1 and 5.3.2
06/01/2017	Section 5.3.4	Revised wording, related to when a consent form should
		be voided and a new form initiated(B,C,D). Added "Do"
		(d.2)
06/01/2017	Section 5.5	Clarified location for name change statement
06/01/2017	Attachment A	Added ICD-10 codes 0UB70ZZ, 0UB73ZZ, 0UB74ZZ,
		0UB77ZZ, 0UB78ZZ. Clarified information regarding
		removal of the entire fallopian tube. (C2). Added "as an
		adjustment". (I.1). Revised instructions for submitting
		inpatient claim for an undocumented alien (I.2). Added the
		word "as"(C.1).

		DRAFT
06/01/2017	Attachment B	Revised information regarding the use of initials and abbreviations for the facility or provider name (A.1). (B). Removed repeat information (C.4). Changed CSC to CSRA (C). Changed unacceptable to not acceptable (A.5). Added BPS as an acceptable abbreviation (B.) Updated instruction for sending sterilization consent forms to CSRA (C, C.1). Removed "May use "Physician on call for Any Provider OB/GYN clinic."" (A.5). Added "This statement must be written on the provider's office letterhead" (E).
06/01/2017	Attachment B and C	Added link for sterilization consent form; https://www.hhs.gov/opa/sites/default/files/consent-for- sterilization-english-updated.pdf and included an updated copy of the consent form.
10/01/2017 10/01/2017	Attachment A (C) Subsections 5.3.4 (b), 5.3.5, 5.4, Attachment B (A)	Updated ICD 10 procedure code list. Added information related to digital signatures. Digital signatures are not acceptable for beneficiary, witness, interpreter, or physician signatures. All signatures must be handwritten.
02/01/2018	Section 5.3.4 (e)Attachment B (27)	Added information related to adding the facility NPI to the top center of the consent form.
08/01/2018	Subsection 5.3	Corrected a format error in the text that was causing a display issue in the Table of Contents. No change to wording or Amended Date.
03/15/2019	Table of Contents	Added, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP."
03/15/2019	All Sections and Attachments	Updated policy template language.
12/31/2019	Table of Contents	Updated policy template language, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP."
12/31/2019	Attachment A	Added, "Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines".
08/15/2020	Subsections 1.1.2, 3.2.2 (c,d), 4.2.3 (a – d), 4.2.4, Attachment A, Attachment B (B).	Essure and hysterosalpingogram procedures are no longer covered by NC Medicaid. Information related to these procedures, including CPT codes for these procedures has been removed from this clinical coverage policy.
08/15/2020	Section 1.0	Revised wording.
08/15/2020	Section 1.1.1	Changed, "doctor" to "physician." Updated the description of a tubal procedure.

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08/15/2020	Section 1.1.2	Added description for Prophylactic Bilateral Salpingectomy.
08/15/2020	Section 2.3	Wording revised and moved to Section 4.2.2.
08/15/2020	Section 2.4	Removed, "Therefore."
08/15/2020	Section 3.2.2	Wording revised and expanded on eligibility requirements.
08/15/2020	Section 4.2.2	(b) and (c) Changed "by" to "under." (d) Added information, related to essure procedures are not a covered service. Noted that Bayer (manufacturer) discontinued sales and distribution of Essure System.
08/15/2020	Section 4.2.3	Added, "Medicaid shall not cover procedures for the." Deleted, "is not covered. Examples of."
08/15/2020	Section 5.3	Added statement that consent required for all voluntary sterilizations including prophylactic bilateral salpingectomy.
08/15/2020	Section 5.3.2	(a) Added, "or childbirth."
08/15/2020	Section 5.3.3	Changed, "estimated" to "expected."
08/15/2020	Section 5.3.4	(d) Added, "Subsection." (e) Changed, "records" to "record." Changed "should also" to "must." Changed "should" to "must." (f) Changed "surgeon" to "physician." Changed "in order for" to "for." Changed "shall" to "must."
08/15/2020	Section 5.3.5	Removed, "will" and "be" and added "are."
08/15/2020	Section 5.5	Removed, "See" and added, "Refer to." Removed, "for an example" and added "regarding."
08/15/2020	Section 5.6	Added words, the, a and procedure.
08/15/2020	Section 7.2 and 7.3	Information from Section 7.2 was moved to Attachment A (H). Information from Section 7.3 was moved to Attachment A (I).
08/15/2020	Attachment A	<ul> <li>(B) Removed, "the purpose of." (C1) Distinguished "open" from "laparoscopic procedures. Added procedure 58661 to "Laparoscopic procedures" table and added procedure 58700 to "Open procedures" table. (C2) Removed Note from C2 restricting entire removal of tube as this is now covered under policy. Removed revenue codes pertaining to Essure procedure and added revenue codes for tubal sterilization billing.</li> </ul>

		Amenueu Date.
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08/15/2020	Attachment B	<ul> <li>(B) Changed abbreviation BPS -Bilateral Postpartum Sterilization to BPPS -Bilateral Postpartum Sterilization.</li> <li>Added PBS- Prophylactic Bilateral Salpingectomy to "acceptable abbreviations" and "acceptable wording" sections. (C) Changed, "CSRA" to "Global Dynamic Integrated Technology (GDIT)." Removed, "Physicians" and "Hospitals." (D) Changed, "included (refer to example below) to "submitted along with the sterilization</li> </ul>
		consent form." (E) Added, "and provider the following information."
08/15/2020	Attachment C	Updated Sterilization Consent form with new Expiration Date of 04/30/2022.
	Section 1.0	Update the definition of "Sterilization" to be consistent with the definition used by CMS Update the name of the procedure from "prophylactic bilateral salpingectomy" to "opportunistic bilateral salpingectomy"
		Update the definition of vasectomy Add the definition of "preterm delivery" and changed any use of the phrase "premature delivery" to "preterm delivery" throughout the policy
	Section 1.1.1	Update the language from "for women who do not want more children" to "for beneficiaries who do not want to become pregnant.
	Section 1.1.2	Updated the definition of Opportunistic Bilateral Salpingectomy
	Section 1.1.3	Updated the definition of vasectomy
	Section 1.1.4	Defined "Preterm delivery"
	Section 2.1.2	Changed "men and women" to "beneficiaries"
	Section 3.2.2 (a)	Removed the reference to the CFR. Now states: "Medicaid shall cover voluntary tubal sterilization procedure or vasectomy for beneficiaries that meet all of the following criteria:"
	Section 3.2.2 (b)	Added "Medicaid shall cover opportunistic bilateral salpingectomy when the beneficiary meets all of the requirements listed in section 3.2.2 (A) and has tested positive for BRCA1 or BRCA2"
	Section 4.2.2	Removed reference to CFR. Changed to "the requirement listed in section 3.2.2 have not been met."
	Section 5.3	Changed "prophylactic bilateral salpingectomy" to "opportunistic bilateral salpingectomy"
	Section 5.3.2	Changed the heading from "Obtaining Consent" to "Obtaining Informed Consent" Added item "d": Under anesthesia or any other substance that affects the beneficiary's ability to provide informed consent.
	Section 5.3.3	Changed the heading from "Date of Confinement" to "Expected Date of Delivery"

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Section 5.3.4	Added "A Consent for Sterilization Form is not required when a beneficiary tests positive for BRCA1 or BRCA2 and requires a risk-reduction salpingo-oophorectomy"
Section 5.3.5	Added the phrase "full (first and last) name" for clairity Removed the signature restriction on the use of initials and abbreviations for the first name of the beneficiary, interpreter, witness, or physician.
Section 5.4	Removed the word "telephone"
Section 5.6	Clarified that reimbursement will be 100% of the allowable amount on the fee schedule or established OMB rate for sterilization procedures
Attachment A	Added: "A printed version of the UB claim must be uploaded with the electronic claim submission with the change to the non-covered column in the "Remarks" field of the UB form (institutional claim form)." And "Note: When a denial is issued, the primary denial reason will always be "Federal Sterilization Consent form required" even if there is an approved consent in the system. Please review the remaining denial reasons for clarification prior to resubmission."
Attachment B	Removed the signature restriction on the use of initials and abbreviations for the first name of the beneficiary, interpreter, witness, or physician. Removed the signature restriction on illegible signatures that forces the claim to permanently deny. Added instructions to complete the Physician Statement portion of the sterilization consent form (line 21). Changed the accepted abbreviation for Opportunistic Bilateral Salpingectomy from "PBS" to "OBS"
Attachment C	Added item number 21 to indicate the location for the new instructions for the Physician Statement

## **Attachment A: Claims-Related Information**

Provider(s) shall comply with the, *NCTracks 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

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.

ICD-10-Code(s)
Z30.2

The only diagnosis code to be considered strictly for elective sterilization is Z30.2, "Encounter for sterilization."

**Note:** All claims must be billed with ICD-10-CM diagnosis code Z30.2 as the primary or secondary diagnosis code on the claim.

#### 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.

#### C1. Physician Claims

<b>Open Procedures</b>		
CPT Code(s)		
58600		
58605		
58611		
58615		
58700		

Laparoscopic Procedures
-------------------------

CPT Code(s)
58661
58670
58671

Vasectomy	Procedures
	1 ()

CPT Code(s)		
552	250	

### C2. Hospital Claims

ICD-10-PCS Code(s)				
0U570ZZ	0UL74CZ	0VBQ3ZZ	0VLQ0CZ	
0U573ZZ	0UL74DZ	0VBQ4ZZ	0VLQ0ZZ	
0U574ZZ	0UL74ZZ	0VBQ8ZZ	0VLQ3CZ	
0U577ZZ	0UL77DZ	0VLH0CZ	0VLQ3ZZ	
0U578ZZ	0UL77ZZ	0VLH0DZ	0VLQ4CZ	
0UB70ZZ	0UL78DZ	0VLH0ZZ	0VLQ4ZZ	
0UB73ZZ	0UL78ZZ	0VLH3CZ	0VLQ8CZ	
0UB74ZZ	0V5H8ZZ	0VLH3DZ	0VLQ8DZ	
0UB77ZZ	0V5L8ZZ	0VLH3ZZ	0VLQ8ZZ	
0UB78ZZ	0V5Q0ZZ	0VLH4CZ	0VTQ0ZZ	
0UL70CZ	0V5Q3ZZ	0VLH4DZ	0VTQ4ZZ	
0UL70DZ	0V5Q4ZZ	0VLH4ZZ	0VLQ0DZ	
0UL70ZZ	0V5Q8ZZ	0VLH8CZ	0VLQ3DZ	
0UL73CZ	0VBH8ZZ	0VLH8DZ	0VLQ4DZ	
0UL73DZ	0VBL8ZZ	0VLH8ZZ		
0UL73ZZ	0VBQ0ZZ			

Revenue Code(s)	
RC 360	
<u>RC 490</u>	

#### **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

Provider(s) shall follow applicable modifier guidelines.

All providers, except ambulatory surgical centers, must append modifier FP to the procedure code when billing for sterilization procedures. Other modifiers must be used, as applicable.

#### E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

#### F. Place of Service

Physicians' offices, ambulatory surgery centers, outpatient clinics, inpatient and outpatient hospitals.

#### G. 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

#### H. Reimbursement

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

Manual review of sterilization claims is performed according to CMS approved guidelines to ensure that the procedure complies with federally mandated guidelines.

#### I. Denied Claims

All provider types submitting claims for reimbursement, such as including any associated services following sterilization, is will be denied or recouped if the sterilization consent form on file is invalid.

#### 1. Additional Information Required

When a claim is denied with an explanation of benefits (EOB) that indicates additional information is required (such as <u>health</u> records to verify a procedure code or a date of service), the claim must be resubmitted as an adjustment with the requested documents and a copy of the valid consent form attached.

#### 2. Undocumented Aliens

When submitting an inpatient hospital claim for a sterilization procedure for an undocumented alien, Providers shall:

- a. submit the claim electronically placing non-emergent charges (such as sterilization) in the Non-Covered column.-A printed version of the UB claim must be uploaded with the electronic claim submission and
- b. note <u>A printed version of the UB claim must be uploaded with the electronic claim</u> submission with the change to the non-covered column in the "Remarks" field of the UB form (institutional claim form).

**Note:** Failure to complete both the Non-Covered column and the Remarks field will result in denial.

**Note:** When a denial is issued, the primary denial reason will always be "Federal Sterilization Consent form required" even if there is an approved consent in the system. Please review the remaining denial reasons for clarification prior to resubmission.

## **Attachment B: Instructions for Completing the Consent Form**

The Sterilization Consent form is available at <u>https://www.hhs.gov/opa/sites/default/files/consent-for-sterilization-english-updated.pdf</u>

#### A. Completing the Form

Following is the list of fields included in the federal consent form requirements for sterilization. All areas are required to be completed except area 9 (race) and areas 10, 11, and 12, if not applicable. Fields in bold print cannot be altered. Once an error is made in these areas, consent form cannot be re-submitted. This guide will assist assists in correct completion of consent forms and should help to decrease the number of denials related to errors in completing the form.

- 1. Person or facility that provided information concerning sterilization. The full name of the person or the full name of the facility providing the information must be stated in this area. Abbreviations of name or abbreviation of facility name are not acceptable. Initials or "doctor on call" are not acceptable.
- 2. Type of sterilization procedure to be performed.
- 3. Beneficiary's date of birth (must be at least 21 years of age when the consent form is signed). Date of birth must match beneficiary files.
- 4. Name of beneficiary as it appears on the Medicaid Identification card.
- 5. The full name of the physician scheduled to do the surgery (abbreviations, initials, or "doctor on call" are not acceptable).
- 6. Type of sterilization procedure to be performed.
- 7. Beneficiary's handwritten signature which must be dated cannot be altered, traced over, or corrected. Initials are not acceptable for the first name. The handwritten signature must be legible. If not, the Beneficiary's name must be typed or printed under the signature. The handwritten signature must be legible. If initials are used for the first name or if the signature is illegible, the Beneficiary's full name must be typed or printed below the signature. Use of a digital signature or signature stamp is not acceptable.
- 8. Date the consent form was signed. The date of the beneficiary's signature must be at least 30 consecutive days and no more than 180 consecutive days prior to the date of the sterilization. The count begins the day following the beneficiary's signature date.
- 9. Race and ethnicity (not required).
- 10. Language in which the form was read to the beneficiary, if an interpreter was used.
- 11. Handwritten signature of the interpreter. Initials are not acceptable for the first name. The handwritten signature must be legible. If initials are used for the first name or if the signature is illegible, the interpreter's full name must be typed or printed below the signature. Use of a digital signature or signature stamp is not acceptable.
- 12. Signature date of the interpreter (same as # 8 and # 16).
- 13. Name of beneficiary.
- 14. Name of sterilization procedure.
- 15. Handwritten signature of person obtaining consent must be dated (see # 16)<mark>. and legible. If not legible, the name must be typed or printed above or below the signature. Initials are not acceptable for the first name. The handwritten signature</mark>

<u>must be legible. If initials are used for the first name or if the signature is illegible, the</u> <u>full name of the person obtaining consent must be typed or printed below the signature.</u> Use of a digital signature or signature stamp is not acceptable.

- 16. Date (this date must be the same as the beneficiary signature date). Note: the doctor can also be the person obtaining consent.
- 17. The full name and address of the facility, including street name and number, city, state, and zip code, where the consent was obtained and witnessed.
- 18. Name of beneficiary.
- 19. Actual date of sterilization. Date of surgery may be changed on consent form with submission of operative records verifying date of service.
- 20. Type of sterilization procedure performed.
- 21. <u>Select the appropriate final paragraph for the Physician's Statement and cross out the paragraph which is not used.</u>
- 22. The box is to be checked if the delivery was premature preterm (write the beneficiary's expected delivery date in the space provided).
- 23. The box is to be checked if emergency abdominal surgery was performed. Claim must be submitted with operative records.
- 24. Physician's handwritten signature must be legible, or name must be printed below the signature. Initials are not acceptable for the first name. The physician's handwritten signature must be legible. If initials are used for the first name or if the signature is illegible, the physician's full name must be typed or printed below the signature. The use of a digital signature or signature stamp is not acceptable. The physician signing the consent shall be the physician who performed the procedure.
- 25. Date must be on or after the date of service.
- 26. The surgeons NPI number must be added to the top left margin of the consent form.
- 27. The beneficiary identification number must be added to the top right margin of the consent form.
- 28. The Facility NPI must be added to the top center of the consent form. This NPI field is for the facility in which the procedure was performed. To ensure that the facility in which the procedure was performed can make inquiries concerning the consent form status, this field must be populated upon the initial submission of the consent form to DHHS fiscal contractor.

#### **B.** Abbreviations **and** Guide for Completion of Sterilization Consent Form

The following abbreviations are acceptable on the sterilization consent form as a description of the type of sterilization procedure:

PBS	Prophylactic bilateral salpingectomy
<b>OBS</b>	<b>Opportunistic bilateral salpingectomy</b>
BPS	Bilateral Partial salpingectomy
BTF	Bilateral tubal fulguration
BTS	Bilateral tubal sterilization
BTC	Bilateral tubal cauterization
BTL	Bilateral tubal ligation
BPPS	Bialteral postpartum sterilization
PPBTL	Postpartum bilateral tubal ligation

LTC Laparoscopic tubal cautery

Acceptable written wording:

Application of fallopian rings/laparoscopic Elective cauterization of fallopian tubes Hulka clip occlusion Laparoscopic tubal ligation Pomeroy Modified Pomeroy Parkland Tubal banding Tubal sterilization Yeon rings Bilateral partial salpingectomy Prophylactic bilateral salpingectomy

Unacceptable wording (not specific to type of procedure):

Tubal coagulation

#### C. Submitting Sterilization Consents

When submitting sterilization consents:

Write the beneficiary's identification number in the upper right corner of the consent form. DHHS fiscal contractor must have the beneficiary identification number to enter the form into the system.

- 1. Verify that all the information on the form is correct.
- 2. Mail the consent to the current DHHS fiscal contractor:

Global Dynamic Integrated Technology (GDIT) PO Box 30968 Raleigh NC 27622

- 3. Upon receipt, DHHS fiscal contractor will review the consent to ensure adherence to federally mandated guidelines.
- 4. File claims electronically, or mail paper claims submitted without a consent to:

GDIT PO Box 30968 Raleigh NC 27622

#### **D.** Name Change Policy for Surgical Procedures

If the beneficiary's name on the claim and the name on the sterilization form are different, a signed name change statement verifying that they are the same person must be submitted along with the sterilization consent form.

#### E. Name Change Statement

The name change statement **must** be written on the provider's office letterhead and provide the following information.

Dr. Any Provider 101 Any Hwy

Any City NC 22222 Beneficiary Identification Number: 88888888T

To Whom It May Concern:

Jane Beneficiary has changed her name to Jane Doe.

Dr. Any Provider (Signature of representative at provider's office is required)

Expiration date: 4/30/2022

## DRAFT Attachment C: The Consent Form

The Sterilization Consent form is available at

https://www.hhs.gov/opa/sites/default/files/consent-for-sterilization-english-updated.pdf

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Form Approved: OMB No. 0937-0166

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#### CONSENT FOR STERILIZATION

NOTICE: YOUR DECISION AT ANY TIME NOT TO BE STERILIZED WILL NOT RESULT IN THE WITHDRAWAL OR WITHHOLDING OF ANY BENEFITS PROVIDED BY PROGRAMS OR PROJECTS RECEIVING FEDERAL FUNDS.

CONSENT TO STERILIZATION

I have asked for and received information about sterilization from

1 . When I first asked

#### Doctor or Clinic

for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits from programs receiving Federal funds, such as Temporary Assistance for Needy Families (TANF) or Medical that I am now getting or for which I may become eligible. I UNDERSTAND THAT THE STERILIZATION MUST BE CONSIDERED

I UNDERSTAND THAT THE STERILIZATION MUST BE CONSIDERED PERMANENT AND NOT REVERSIBLE. I HAVE DECIDED THAT I DO NOT WANT TO BECOME PREGNANT, BEAR CHILDREN OR FATHER CHILDREN.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be stertized.

I understand that I will be sterilized by an operation known as a 2. The discomforts, risks

Specify Type of Operation

and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

my questions have been answered to my satisfaction. I understand that the operation will not be done until at least 30 days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by federally funded programs. 3



#### INTERPRETER'S STATEMENT

If an interpreter is provided to assist the individual to be sterilized: I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent form in 10language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation.

11 12 Interpreter's Signature Date

HHS-687 (04/22)

STATEMENT OF PERSON OBTAINING CONSENT
Before 13 signed the
Name of Individual
consent form, I explained to him/her the nature of sterilization operation
14 , the fact that it is
Specify Type of Operation
Intended to be a final and ineversible procedure and the discomforts, risks
and benefits associated with it.

I counseled the individual to be sterilized that atternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent. I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequences of the procedure.

15		16		
Signature of Person Obtaining Consent		Date		
17				
Facility				
Address				
PHYSICIAN'S STATEMENT				
Shortly before I performed a sterilization operation upon				
18	on	19		
Name of Individual	-	Date of Sterilization		

l explained to him/her the nature of the sterilization operation
20
, the fact that it is
Specify Type of Operation

Intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent. I informed the individual to be sterilized that his/her consent can

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

(instructions for use of alternative final paragraph: Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery where the sterilization is performed less than 30 days after the date of the individual's signature on the consent form. In those cases, the second paragraph below must be used. Cross out the paragraph which is not used.) 21

(1) At least 30 days have passed between the date of the individual's signature on this consent form and the date the sterilization was performed.

(2) This sterilization was performed less than 30 days but more than 72 hours after the date of the individual's signature on this consent form because of the following circumstances (check applicable box and fill in information requested): 22

Premature delivery

Individual's expected date of delivery:

Emergency abdominal surgery (describe circumstances): 23

