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1.0 Description of the Procedure, Product, or Service

Sterilization is any medical procedure, treatment, or operation for the purpose of rendering a beneficiary permanently incapable of reproducing. Sterilization is a permanent method of birth control. Sterilization procedures for women are called tubal occlusion. The procedure for men is called vasectomy.

1.1 Definitions

1.1.1 Tubal Procedure

Female sterilization, also called tubal occlusion or ligation, is a permanent contraceptive method for women who do not want more children. The method requires a simple surgical procedure that prevents the egg from passing down the fallopian tubes into the uterus. A physician doctor 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 pubic 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.

Hysteroscopic Procedure

The hysteroscopic approach to permanent sterilization, also known as the Essure System, does not require an incision or general anesthesia. It is indicated for women who desire permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes. A hysteroscope is inserted through the vagina and cervix into the uterus for direct visualization. Next, a small catheter with the micro-insert mounted at the tip is inserted through the hysteroscope into each of the fallopian tubes (one at a time) and the micro-inserts are released. The micro-inserts irritate the lining of the fallopian tube, causing the growth of scar tissue and the eventual permanent blockage of the fallopian tube.

1.1.2 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.
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

Medicaid

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

NCHC

NCHC 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/provider-manuals.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 Mental Competency

The beneficiary must be mentally competent.

Note: If a judicial court orders a sterilization for a beneficiary who is a ward of the county and is mentally incompetent, Medicaid is not responsible for the reimbursement of the sterilization.

2.4 Undocumented Aliens

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

Medicaid shall cover voluntary sterilization procedures for a beneficiary that meets requirements found in 42 CFR Part 441, Subpart F – Sterilization and this clinical coverage policy. Including, a beneficiary who:

a. is at least 21 years of age at time of the informed consent is signed;

b. is not legally declared to be mentally incompetent;

c. is not one of the following:

1. 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

2. 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

d. gave informed consent.
This service covers procedures for both men and women, age 21 and over at the
time of informed consent, products, and services related to this policy when they
are medically necessary and:
(a) the beneficiary meets the eligibility requirements listed in Section 2.0; and
(b) the procedure is provided according to the federal regulations listed in 42
CFR Part 441, Subpart F—Sterilization.

3.2.3 Hysterosalpingogram
For beneficiaries who have undergone the Essure sterilization procedure, this service covers a separate hysterosalpingogram (HSG) to confirm occlusion of the fallopian tubes, three to four months after placement of the micro-inserts.

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;
(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 procedures, products, and services related to this policy when:
(a) the procedure is not provided according to 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;
(c) the beneficiary is an institutionalized individual, as defined under 42 CFR 441.251.
d. 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.

**Essure System Contraindications**

The Essure System should not be used in any beneficiary who:

a. is uncertain about her desire to end fertility;

b. can have only one micro-insert inserted (including patients with apparent contralateral proximal tubal occlusion and patients with a suspected unicornuate uterus);

c. has previously undergone a tubal ligation; or

d. has any of the following conditions:

1. pregnancy or suspected pregnancy;
2. delivery or termination of a pregnancy less than six weeks before Essure micro-insert placement;
3. active or recent upper or lower pelvic infection;
4. known allergy to contrast media; or
5. known hypersensitivity to nickel, confirmed by skin test.

### 4.2.3 Post-Procedure Hysterosalpingogram

Post-procedure HSG is not covered for any condition or diagnosis other than confirmation of occlusion of the fallopian tubes after the Essure sterilization procedure.

### 4.2.3 Sterilization Reversals

Medicaid shall not cover procedures for the reversal of sterilization.

Examples of Sterilization reversal procedures 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

The beneficiary shall provide voluntary informed consent according to the requirement found in accordance with 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, days prior to the date of the sterilization, except under the following circumstances:

a. Premature Delivery: Informed consent must have been given at least 30 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 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.

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

5.3.3 Date of Confinement

The EDD expected estimated date of delivery confinement (date of delivery) must be documented on the sterilization consent form in cases of premature delivery.
5.3.4 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 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);
   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 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 records. A copy of this consent form must be provided to the beneficiary. Copies must be also 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 should be retained at the service site where the consent is being obtained.

f. Providers shall add a valid 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, in order for the form to be processed. The facility NPI in which the procedure was performed shall 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.
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 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 will not be 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. 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 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. (See Refer to Attachment B (E), for an example 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% reimbursement of the allowable amount on the fee schedule 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 will be suspended for medical review. Health records may 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).

7.2 Claims Review

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

7.3 Claims Reimbursement

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

8.0 Policy Implementation and History

Original Effective Date: January 1, 1974

History:

<table>
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<th>Date</th>
<th>Section Revised</th>
<th>Change</th>
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<tr>
<td>07/01/2008</td>
<td>Subsections 1.2, 4.1.1, 3.2, 4.2, and Attachment A</td>
<td>Coverage of the Essure System procedure (effective with N.C. Medicaid approval date, September 1, 2003) and the hysterosalpingogram procedure (effective with N.C. Medicaid approval date, December 1, 2003) was added to the policy.</td>
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<tr>
<td>03/12/2012</td>
<td>all sections and attachment(s)</td>
<td>Technical changes to merge Medicaid and NCHC current coverage into one policy.</td>
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<tr>
<td>07/01/2013</td>
<td>Section 5.3.4</td>
<td>Added information regarding consent form changes.</td>
</tr>
<tr>
<td>07/01/2013</td>
<td>Section 5.3.5</td>
<td>Added information regarding acceptable signatures, signature stamps usage, and use of initials.</td>
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<tr>
<td>07/01/2013</td>
<td>Section 5.4</td>
<td>Changed wording from “should” to “must” in (a).</td>
</tr>
<tr>
<td>07/01/2013</td>
<td>Attachment B</td>
<td>Changes made in #’s 7, 11, 15, and 23 regarding the use of initials and signature stamps.</td>
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<tr>
<td>07/01/2013</td>
<td>Attachment C</td>
<td>Added new consent form approved by CMS.</td>
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<tr>
<td>07/01/2013</td>
<td>All sections and attachment(s)</td>
<td>Replaced “recipient” with “beneficiary.”</td>
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<tr>
<td>10/01/2015</td>
<td>All sections and Attachments</td>
<td>Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.</td>
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<tr>
<td>06/01/2017</td>
<td>All Sections</td>
<td>Updated CFR 441.250 through 259 to 42 CFR Part 441, Subpart F - Sterilization.</td>
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<tr>
<td>06/01/2017</td>
<td>All Sections</td>
<td>Changed DMA fiscal agent to DHHS fiscal contractor.</td>
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<tr>
<td>06/01/2017</td>
<td>All Sections</td>
<td>Replaced “recipient” with “beneficiary.”</td>
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<tr>
<td>06/01/2017</td>
<td>All Sections</td>
<td>Changed medical record to health record.</td>
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<tr>
<td>06/01/2017</td>
<td>Section 4.2.2</td>
<td>Clarified definition of mentally incompetent individual and institutionalized individual.</td>
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<tr>
<td>06/01/2017</td>
<td>Section 5.2</td>
<td>Updated 5.2.1 and 5.2.2. PA is not a requirement for a sterilization procedure.</td>
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<tr>
<td>06/01/2017</td>
<td>Section 5.3, 5.3.1, 5.3.2</td>
<td>Added 42 CFR 441.253 and deleted language found in CFR(s) in sections 5.3.1 and 5.3.2</td>
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<td>06/01/2017</td>
<td>Section 5.3.4</td>
<td>Revised wording, related to when a consent form should be voided and a new form initiated(B,C,D). Added “Do” (d.2)</td>
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<td>06/01/2017</td>
<td>Section 5.5</td>
<td>Clarified location for name change statement</td>
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<td>06/01/2017</td>
<td>Attachment A</td>
<td>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).</td>
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<td>06/01/2017</td>
<td>Attachment B</td>
<td>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).</td>
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<td>10/01/2017</td>
<td>Attachment A (C)</td>
<td>Updated ICD 10 procedure code list.</td>
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<tr>
<td>10/01/2017</td>
<td>Subsections 5.3.4</td>
<td>Added information related to digital signatures. Digital signatures are not acceptable for beneficiary, witness, interpreter, or physician signatures. All signatures must be handwritten.</td>
</tr>
<tr>
<td>02/01/2018</td>
<td>Section 5.3.4</td>
<td>Added information related to adding the facility NPI to the top center of the consent form.</td>
</tr>
<tr>
<td>08/01/2018</td>
<td>Subsection 5.3</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Subsections 1.1.2, 3.2.2 (c,d), 4.2.3 (a, d), 4.2.4, Attachment A, Attachment B (B).</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Section 1.0</td>
<td>Revised wording.</td>
</tr>
<tr>
<td></td>
<td>Section 1.1.1</td>
<td>Changed, “doctor” to “physician.”</td>
</tr>
<tr>
<td></td>
<td>Section 2.3</td>
<td>Wording revised and moved to Section 4.2.2.</td>
</tr>
<tr>
<td></td>
<td>Section 2.4</td>
<td>Removed, “Therefore.”</td>
</tr>
<tr>
<td>Section 3.2.2</td>
<td>Wording revised and expanded on eligibility requirements.</td>
<td></td>
</tr>
<tr>
<td>-------------</td>
<td>--------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Section 4.2.2</td>
<td>(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.</td>
<td></td>
</tr>
<tr>
<td>Section 4.2.3</td>
<td>Added, “Medicaid shall not cover procedures for the.” Deleted, “is not covered. Examples of:”</td>
<td></td>
</tr>
<tr>
<td>Section 5.3.2</td>
<td>(a) Added, “or childbirth.”</td>
<td></td>
</tr>
<tr>
<td>Section 5.3.3</td>
<td>Changed, “estimated” to “expected.”</td>
<td></td>
</tr>
<tr>
<td>Section 5.3.4</td>
<td>(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.”</td>
<td></td>
</tr>
<tr>
<td>Section 5.3.5</td>
<td>Removed, “will” and “be” and added “are.”</td>
<td></td>
</tr>
<tr>
<td>Section 5.5</td>
<td>Removed, “See” and added, “Refer to.” Removed, “for an example” and added “regarding.”</td>
<td></td>
</tr>
<tr>
<td>Section 5.6</td>
<td>Added words, the, a and procedure.</td>
<td></td>
</tr>
<tr>
<td>Section 7.2 and 7.3</td>
<td>Information from Section 7.2 was moved to Attachment A (H). Information from Section 7.3 was moved to Attachment A (I).</td>
<td></td>
</tr>
<tr>
<td>Attachment A</td>
<td>(B) Removed, “the purpose of.” C2 Changed, “should” to “must.”</td>
<td></td>
</tr>
<tr>
<td>Attachment B</td>
<td>(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 consent form.” (E) Added, “and provider the following information.”</td>
<td></td>
</tr>
</tbody>
</table>
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)

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.

<table>
<thead>
<tr>
<th>ICD-10-Code(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z30.2</td>
</tr>
</tbody>
</table>

The only diagnosis code to be considered strictly for the purpose of 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

Laparoscopic Procedures

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<thead>
<tr>
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<tbody>
<tr>
<td>58600</td>
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<tr>
<td>58605</td>
</tr>
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Essure Procedure

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<td>58570</td>
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Hysterosalpingogram

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<tr>
<td>58340</td>
</tr>
<tr>
<td>74740</td>
</tr>
</tbody>
</table>

Note: CPT procedure code 58340 must be billed on the same date of service as procedure code 74740.

Vasectomy Procedures

<table>
<thead>
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<tbody>
<tr>
<td>55250</td>
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C2. Hospital Claims

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<tr>
<td>0UL73DZ</td>
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<table>
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<table>
<thead>
<tr>
<th>ICD-10-PCS Code(s)</th>
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</thead>
<tbody>
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</tr>
<tr>
<td>0VLQ3DZ</td>
</tr>
<tr>
<td>0VLQ4DZ</td>
</tr>
</tbody>
</table>

Note: Removal of the entire fallopian tube is not acceptable, unless medically necessary. If it is necessary to remove the entire fallopian tube, documentation to support medical necessity **must** be submitted with the completed consent form.

Revenue Code(s)

<table>
<thead>
<tr>
<th>Revenue Code(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RC 278</td>
</tr>
<tr>
<td>RC 320</td>
</tr>
</tbody>
</table>
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, including any associated services following sterilization, 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 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 the change in the Remarks field.

Note: Failure to complete both the Non-Covered column and the Remarks field will result in denial.
Attachment B: Instructions for Completing the Consent Form


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 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. 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 days and no more than 180 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. 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) 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. 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.
DRAFT

20. Type of sterilization procedure performed.
21. The box is to be checked if the delivery was premature (write the beneficiary’s expected delivery date in the space provided).
22. The box is to be checked if emergency abdominal surgery was performed. Claim must be submitted with operative records.
23. Physician’s handwritten signature must be legible or name must be printed below the signature. **Initials are not acceptable for the first name. 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.
24. Date must be on or after the date of service.
25. The surgeons NPI number must be added to the top left margin of the consent form.
26. The beneficiary identification number must be added to the top right margin of the consent form.
27. 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/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:
- **BPS** Bilateral Partial salpingectomy
- **BTF** Bilateral tubal fulguration
- **BTS** Bilateral tubal sterilization
- **BTC** Bilateral tubal cauterization
- **BTL** Bilateral tubal ligation
- **BPS** Bilateral postpartum sterilization
- **PPBTL** Postpartum bilateral tubal ligation
- **LTC** Laparoscopic tubal cauterization

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
- Essure system
- Bilateral partial 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:
   - CSRA 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:
   - (Physicians)
     GDIT CSRA
     PO Box 30968
     Raleigh NC 27622
   - (Hospitals)
     CSRA
     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 included (refer to example below).

E. Name Change Statement (Example)

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)
Attachment C: The Consent Form