Department:	Medical Management	**Original Approval:**	01/26/2011
Policy #:	MM143	**Last Approval:**	03/01/2019
Title:	Sterilization and Hysteroscopic Sterilization		
Approved By:	UM Medical Subcommittee		

Required Documentation:

- History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service
- All previous treatments for the problem, including dates and the patient's response to the treatment
- Imaging studies and lab values if pertinent
- Specifics about the device to be used (if the use of a device is proposed).
- Informed consent from the member dated at least 30 days and not more than 180 days from the date of the procedure.

BACKGROUND

Hysteroscopic tubal sterilization is accomplished by placement of implants within the fallopian tubes. This procedure, performed only by trained providers, is done in the outpatient setting. Using a hysteroscopic approach, one Essure System is placed in the proximal section of each fallopian tube lumen. The Essure System expands upon release, acutely anchoring itself in the fallopian tube and subsequently elicits a benign tissue response. Tissue in-growth into the Essure System anchors the device and occludes the fallopian tube, resulting in sterilization.

The Health Care Authority (HCA) has reviewed available research on available device systems to achieve tubal sterilization, as has a CHPW Medical Director. At this time, only the Essure System has been investigated sufficiently in long-term studies to demonstrate adequate safety and efficacy. The Essure System was approved by the Food and Drug Administration in 2002. Several subsequent revisions to the system have also been approved.

Approval of the Essure System by the FDA was based on the results of a Phase III clinical trial involving 518 sexually active reproductive-age women who underwent a placement procedure. The Essure System was reported to be 98 % effective in preventing pregnancy after 2 years follow-up.

Available data shows that this procedure is at least as safe and effective as other current sterilization procedures, or better.

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DEFINITIONS

Sterilization is any medical procedure, treatment, or operation for the purpose of rendering a client permanently incapable of reproducing. Options for sterilization include for males: vasectomy; for females: tubal ligation and hysteroscopic tubal sterilization. Hysteroscopic tubal sterilization is described in more detail because of changes in approved devices.

INDICATIONS/CRITERIA

Medicaid Members	***Continue to criteria for approval below.***
Medicare Members	

Indications For Hysteroscopic Tubal Sterilization

CHPW considers hysteroscopic tubal sterilization/transcervical sterilization (e.g., the Essure System) medically necessary for women who desire permanent birth control by bilateral occlusion of the fallopian tubes.

CHPW considers hysteroscopic tubal sterilization/transcervical sterilization (e.g., the Essure System) experimental and investigational for all other indications (e.g., hydrosalpinx).

Contraindications For Hysteroscopic Tubal Sterilization

Hysteroscopic tubal sterilization is contraindicated for women with any of the following conditions:

- Active or recent upper or lower pelvic infection; *or*
- Delivery or termination of a pregnancy less than 6 weeks before occlusion device placement; *or*
- Known allergy to contrast media or known hypersensitivity to nickel confirmed by skin test; *or*
- Pregnancy or suspected pregnancy.

Sterilization Clinical Coverage Criteria:

For Medicare Members:

CHPW uses Centers for Medicare and Medicaid National Coverage Determination (CMS NCD): https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=13, which states that sterilizations are not covered unless the treatment is a necessary part of treatment of an illness or injury.

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Indications and Limitations of Coverage

A. Nationally Covered Conditions

- Payment may be made only where sterilization is a necessary part of the treatment of an illness or injury, e.g., removal of a uterus because of a tumor, removal of diseased ovaries.

- Sterilization of a mentally challenged beneficiary is covered if it is a necessary part of the treatment of an illness or injury (bilateral oophorectomy or bilateral orchidectomy in a case of cancer of the prostate). The Medicare Administrative Contractor denies claims when the pathological evidence of the necessity to perform any such procedures to treat an illness or injury is absent; and

- Monitor such surgeries closely and obtain the information needed to determine whether in fact the surgery was performed as a means of treating an illness or injury or only to achieve sterilization.

B. Nationally Non-Covered Conditions

- Elective hysterectomy, tubal ligation, and vasectomy, if the primary indication for these procedures is sterilization;

- A sterilization that is performed because a physician believes another pregnancy would endanger the overall general health of the woman is not considered to be reasonable and necessary for the diagnosis or treatment of illness or injury within the meaning of §1862(a)(1) of the Social Security Act. The same conclusion would apply where the sterilization is performed only as a measure to prevent the possible development of, or effect on, a mental condition should the individual become pregnant; and sterilization of a mentally retarded person where the purpose is to prevent conception, rather than the treatment of an illness or injury.

For Medicare SNP members:

When a member's coverage is Medicare SNP, Medicare is primary and the member also has Apple Health (Medicaid) coverage as secondary. Since sterilization procedures are not covered under Medicare, the coverage is under Apple Health, which does cover sterilization procedures. The same criteria for Apple Health Members apply (below).

For WA Apple Health Members:

CHPW covers sterilization procedures for members 21 years and older. Members younger than 21 have access to fee for service coverage from the Health Care Authority but not through CHPW.

Criteria for Sterilizations For Apple Health Members

CHPW uses the criteria in the WAC 182-531-1550, for sterilizations in general and the additional

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criteria for hysteroscopic sterilization:

Criteria For All Sterilizations

1. The Medicaid agency covers sterilization when all of the following apply:

   (a) The client is at least eighteen years of age at the time an agency-approved consent form is signed;
   (b) The client is a mentally competent individual;
   (c) The client participates in a medical assistance program (see WAC 182-501-0060);
   (d) The client has voluntarily given informed consent; and
   (e) The date the client signed the sterilization consent is at least thirty days and not more than one hundred eighty days before the date of the sterilization procedure.

2. Any Medicaid provider who is licensed to do sterilizations within their scope of practice may provide vasectomies and tubal ligations to any Medicaid client. (See subsections (10), (11), and (12) of this section for additional qualifications of providers performing hysteroscopic sterilizations.)

3. The Medicaid agency requires at least a seventy-two hour waiting period rather than the usual thirty-day waiting period for sterilization in either of the following circumstances:

   (a) At the time of a premature delivery when the client gave consent at least thirty days before the expected date of delivery. (The expected date of delivery must be documented on the consent form.)
   (b) For emergency abdominal surgery. (The nature of the emergency must be described on the consent form.)

4. The Medicaid agency waives the thirty-day consent waiting period for sterilization when the client requests that sterilization be performed at the time of delivery and completes a sterilization consent form. One of the following circumstances must apply:

   (a) The client became eligible for medical assistance during the last month of pregnancy;
   (b) The client did not obtain medical care until the last month of pregnancy; or
   (c) The client was a substance abuser during pregnancy, but is not using alcohol or illegal drugs at the time of delivery.

5. The Medicaid agency does not accept informed consent obtained when the client is:

   (a) In labor or childbirth; or
   (b) In the process of seeking to obtain or obtaining an abortion; or
   (c) Under the influence of alcohol or other substances, including pain medications for labor and delivery, that affects the client's state of awareness.

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6. The Medicaid agency has certain consent requirements that the provider must meet before the agency reimburses sterilization of an institutionalized client or a client with mental incompetence. The agency requires both of the following:

   (a) A court order, which includes both a statement that the client is to be sterilized, and the name of the client's legal guardian who will be giving consent for the sterilization; and
   (b) A sterilization consent form signed by the legal guardian, sent to the agency at least thirty days before the procedure.

7. The Medicaid agency reimburses epidural anesthesia in excess of the six-hour limit for deliveries if sterilization procedures are performed in conjunction with or immediately following a delivery.

   (a) For reimbursement, anesthesia time for sterilization is added to the time for the delivery when the two procedures are performed during the same operative session.
   (b) If the sterilization and delivery are performed during different operative sessions, the anesthesia time is calculated separately.

8. The Medicaid agency reimburses all attending providers for the sterilization procedure only when the provider submits an agency-approved and complete consent form with the claim for reimbursement. (See subsections (10), (11), and (12) of this section for additional coverage criteria for hysteroscopic sterilizations.)

   (a) The physician must complete and sign the physician statement on the consent form within thirty days of the sterilization procedure.
   (b) The agency reimburses attending providers after the procedure is completed.

Additional Criteria Regarding Hysteroscopic Sterilizations

9. The Medicaid agency pays for hysteroscopic sterilizations when the following additional criteria are met:

   (a) A device covered by the agency is used.
   (b) The procedure is predominately performed in a clinical setting, such as a physician's office, without general anesthesia and without the use of a surgical suite; and is covered according to the corresponding agency fee schedule.
   (c) If determining that it is medically necessary to perform the procedure in an inpatient rather than outpatient setting, a provider must submit clinical notes with the claim, documenting the medical necessity.
   (d) The client provides informed consent for the procedure.

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(e) The provider performing hysteroscopic sterilization with the Essure device must be registered with HCA as an Approved Provider in order to receive prior authorization to perform procedures for CHPW APPLE HEALTH members.

a. Link to list of HCA-approved hysteroscopic sterilization providers: https://www.hca.wa.gov/assets/billers-and-providers/hysteroscopic_sterilization.pdf (checked 2/24/2019)

LIMITATIONS/EXCLUSIONS

Please refer to a product line's certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides
WASHINGTON APPLE HEALTH	http://chpw.org/our-plans/apple-health/
INTEGRATED MANAGED CARE	http://chpw.org/our-plans/apple-health/

Citations & References

CFR		
WAC		
RCW		
Contract Citation	☒ WAH	16.3 Sterilizations and Hysterectomies
	☒ IMC	
	☒ MA	
Other Requirements		
NCQA Elements	UM2	
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Revision History

Revision Date	Revision Description	Revision Made By
01/19/2011	Original draft	Lucy Sutphen, MD, FACP
01/26/2011	Approval	MMLT
12/14/2011	Approval	MMLT
11/28/2012	Approval	MMLT
04/08/2014	Added details of and links to requirements under WA APPLE HEALTH. Removed restrictions that might limit member choice of provider for MEDICARE ADVANTAGE and COMMERCIAL Lines of Business.	MMLT
04/08/2015	Approval	MMLT
04/01/2016	Updated links, references and citations, including addition AH FIMC as separate line of business with its own benefit book	Kate Brostoff MD
04/06/2016	Approval	MMLT
04/10/2017	Updated links, removed references to Adiana which is off the market, corrected name of Essure from Essure micro-implant to Essure System.	LuAnn Chen, MD
04/12/2017	Minor Editing	Cyndi Stilson, RN
04/12/2017	Approval	MMLT
03/26/2018	Moved from UM019	Cindy Bush
03/27/2018	Links checked, Clarification that the criteria for Medicaid coverage of sterilization procedures is from WAC 182-531-1550 and criteria details added to the policy. Clarified that sterilization is not covered for Medicare members. Changed the title from hysteroscopic sterilization to sterilization and hysteroscopic sterilization.	LuAnn Chen, MD
04/06/2018	Transferred to new template	Cindy Bush
04/10/2018	Approval	UM Medical Subcommittee
02/24/2019	Specified that Medicare SNP members have same sterilization coverage and	LuAnn Chen, MD

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	crteria as Apple Health Members. Added required documentation.	
03/01/2019	Approval	UM Medical Subcommittee

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