

MEDICAL POLICY



SUBJECT: FEMALE STERILIZATION	EFFECTIVE DATE: 08/28/03
POLICY NUMBER: 4.01.07	REVISED DATE: 09/23/04, 08/25/05, 06/22/06, 06/28/07, 06/26/08, 08/27/09, 08/26/10, 08/25/11, 08/23/12, 08/22/13, 08/28/14, 08/27/15, 08/25/16, 08/25/17, 10/25/18
CATEGORY: Contract Clarification	PAGE: 1 OF: 5

- *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.*
- *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.*
- *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT:

- I. The Health Plan provides benefits for female sterilization in accordance with the Preventive Services for Women portion of the Affordable Care Act, when applicable (*refer to the Description section for further information*).
- II. When the Affordable Care Act does not apply medical appropriateness for female sterilization performed by tubal ligation or occlusion via a laparoscopic, open, or hysteroscopic approach will be based on our criteria and review of the peer-reviewed literature and considered **medically appropriate** when:
 - A. all other forms of contraception (e.g., oral and injectable hormones, intrauterine devices, condoms, etc.) are contraindicated; and
 - B. pregnancy will present a health risk to the patient.

An example of a sterilization that could be considered medically appropriate would be a woman with severe cardiovascular disease in whom pregnancy could be life threatening and all other forms of contraception are contraindicated.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Sterilization is a means of permanently preventing pregnancy by rendering the patient infertile. In women, sterilization is generally performed by tubal ligation or occlusion, either laparoscopically or as an open surgical procedure.

In 2002, the U.S. Food and Drug Administration (FDA) approved the first transcervical hysteroscopically placed sterilization method using the Essure® System. The Essure® System involves the bilateral insertion of micro-inserts into the fallopian tubes. The micro-inserts cause scarring and occlusion in the fallopian tubes, resulting in permanent sterilization. As of December 2018, Essure permanent birth control device will no longer be sold or distributed by Bayer.

In 2009, the FDA granted pre-market approval of the Adiana® permanent contraception system (Hologic, Inc.), a second transcervical hysteroscopically placed sterilization system. In the Adiana® system a low level of radiofrequency is delivered to the intramural segment of each fallopian tube in order to create a lesion. A small polymer matrix insert is then placed into each fallopian tube. Tissue ingrows around the inserts and eventually occludes the fallopian tubes; which renders the patient infertile. According to a February 2013 practice bulletin published by the American College of Obstetricians and Gynecologists (ACOG), the *Adiana® system is no longer manufactured* because of financial reasons and is no longer available for use.

A hysterosalpingogram is performed 3 months after implantation in order to verify occlusion and may be performed again at 6 months if the initial hysterosalpingogram did not show occlusion.

For contracts that do not include coverage for elective sterilization, benefits are provided when the Health Plan determines female sterilization is medically appropriate.

SUBJECT: FEMALE STERILIZATION POLICY NUMBER: 4.01.07 CATEGORY: Contract Clarification	EFFECTIVE DATE: 08/28/03 REVISED DATE: 09/23/04, 08/25/05, 06/22/06, 06/28/07, 06/26/08, 08/27/09, 08/26/10, 08/25/11, 08/23/12, 08/22/13, 08/28/14, 08/27/15, 08/25/16, 08/25/17, 10/25/18 PAGE: 2 OF: 5
--	--

According to the Preventive Services for Women portion of the Affordable Care Act Under section 2713 of the Public Health Services Act non-grandfathered group health plans are required to provide coverage in-network without cost sharing for sterilization for all women with reproductive capacity in the first plan year that begins on or after August 1, 2012. Group health plans sponsored by certain religious employers, and group health insurance coverage in connection with such plans, may be exempt from the requirement to cover contraceptive services, including female sterilization.

The HRSA-supported Women’s Preventive Services Guidelines were originally established in 2011 based on recommendations from a Department of Health and Human Services' commissioned study by the Institute of Medicine (IOM), now known as the National Academy of Medicine (NAM). The Women’s Preventive Services Initiative recommends that the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures be available as part of contraceptive care. The full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration include: (1) sterilization surgery for women, (2) surgical sterilization via implant for women, (3) implantable rods, (4) copper intrauterine devices, (5) intrauterine devices with progestin (all durations and doses), (6) the shot or injection, (7) oral contraceptives (combined pill), (8) oral contraceptives (progestin only, and), (9) oral contraceptives (extended or continuous use), (10) the contraceptive patch, (11) vaginal contraceptive rings, (12) diaphragms, (13) contraceptive sponges, (14) cervical caps, (15) female condoms, (16) spermicides, and (17) emergency contraception (levonorgestrel), and (18) emergency contraception (ulipristal acetate), and additional methods as identified by the FDA. Additionally, instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method.

RATIONALE:

Female sterilization by ligation or transection of the fallopian tubes is a surgical procedure and not subject to FDA regulation. The FDA approved the Essure® System on November 4, 2002 and the Adiana® system on July 7, 2009 as hysteroscopic means of permanent sterilization.

The U.S. Food and Drug Administration was notified by Bayer that the Essure permanent birth control device will no longer be sold or distributed after December 31, 2018. This decision follows the FDA’s patient safety action in April, in which the agency issued an order restricting the sale and distribution of Essure; it was a unique type of restriction where the FDA used its authority to impose additional requirements to provide a reasonable assurance of the device’s safety and effectiveness. The device has been associated with serious risks including persistent pain, perforation of the uterus and fallopian tubes, and migration of the coils into the pelvis or abdomen. This method of permanent birth control, where coils are inserted into the fallopian tubes creating a blockage that prevents the passage of an egg from the ovary, has been associated with numerous adverse events that were reported to the FDA including a significant collection of recent reports that have mentioned issues involving surgery to remove the device.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

<u>CPT:</u>	58565	Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants
	58600	Ligation or transection of fallopian tube(s), abdominal or vaginal approach, unilateral or bilateral
	58605	Ligation or transection of fallopian tube(s), abdominal or vaginal approach, postpartum, unilateral or bilateral, during same hospitalization (separate procedure)

SUBJECT: FEMALE STERILIZATION POLICY NUMBER: 4.01.07 CATEGORY: Contract Clarification	EFFECTIVE DATE: 08/28/03 REVISED DATE: 09/23/04, 08/25/05, 06/22/06, 06/28/07, 06/26/08, 08/27/09, 08/26/10, 08/25/11, 08/23/12, 08/22/13, 08/28/14, 08/27/15, 08/25/16, 08/25/17, 10/25/18 PAGE: 3 OF: 5
--	--

- 58611 Ligation or transection of fallopian tube(s) when done at the time of cesarean delivery or intra-abdominal surgery (not a separate procedure)
 - 58615 Occlusion of fallopian tube(s) by device (eg, band, clip, Falope ring) vaginal or suprapubic approach
 - 58670 Laparoscopy, surgical; with fulguration of oviducts (with or without transection)
 - 58671 with occlusion of oviducts by device (eg, band, clip, or Falope ring)
- Copyright © 2018 American Medical Association, Chicago, IL*
- HCPCS:** A4264 (E/I) Permanent implantable contraceptive intratubal occlusion device(s) and delivery system
- ICD10:** Z30.2 Encounter for sterilization
- Z98.51 Tubal ligation status

REFERENCES:

Adelman MR, et al. Management of complications encountered with Essure hysteroscopic sterilization: a systematic review. J Minim Invasive Gynecol 2014 Sep-Oct;21(5):733-43.

Antoun A., et al The feasibility, safety, and effectiveness of hysteroscopic sterilization compared with laparoscopic sterilization. J. Obstet Gynecol 2017;217:570.e1-6

*BlueCross BlueShield Association. Hysteroscopic placement of micro-inserts in the fallopian tubes as a form of permanent sterilization - Archived. Medical Policy Reference Manual Policy #4.01.13. 2009 Dec 10.

*BlueCross BlueShield Association. Birth control – Archived. Medical Policy Reference Manual Policy #4.02.03. 2009 Oct 6.

Casey J, et al. Current techniques and outcomes in hysteroscopic sterilization: current evidence, considerations, and complications with hysteroscopic sterilization micro inserts. Curr Opin Obstet Gynecol. 2017 Aug;29(4):218-224.

Centers for Disease Control and Prevention. U. S. selected practice recommendations for contraceptive use, 2016. MMWR 2016 Jul 29;65(3):1-104.

Centers for Disease Control and Prevention. U. S. medical eligibility criteria for contraceptive use, 2016. MMWR 2016 Jul 29;65(4):1-66.

*Cooper JM, et al. Microinsert nonincisional hysteroscopic sterilization. Obstet Gynecol 2003 Jul;102(1):59-67.

Faculty of Sexual & Reproductive Healthcare (FSRH). Guidance on Male and Female Sterilisation. 2014 Sep [https://www.fsrh.org/documents/cec-ceu-guidance-sterilisation-cpd-sep-2014/] accessed 9/5/18.

Gizzo S, et al. Female sterilization: update on clinical efficacy, side effects and contraindications. Minim Invasive Ther Allied Technol 2014 Oct;23(5):261-70.

Health Resources & Services Administration (HRSA), Women’s Preventive Services Guidelines [https://www.hrsa.gov/womensguidelines2016/index.html] accessed 9/5/18.

Institute of Medicine. National Academies Press. Clinical Preventive Services for Women: Closing the Gaps. Committee on Preventive Services for Women. 2011 [http://www.nap.edu/catalog.php?record_id=13181] accessed 9/5/18.

la Chapelle CF, et al. Effectiveness and feasibility of hysteroscopic sterilization techniques: a systematic review and meta-analysis. Fertil Steril 2015 Jun;103(6):1516-25.e1-3.

Lane A, et al. Providing Re-Essure-ance to the Nickel-Allergic Patient Considering Hysteroscopic Sterilization .J Minim Invasive Gynecol. 2016 Jan;23(1):126-9.

SUBJECT: FEMALE STERILIZATION POLICY NUMBER: 4.01.07 CATEGORY: Contract Clarification	EFFECTIVE DATE: 08/28/03 REVISED DATE: 09/23/04, 08/25/05, 06/22/06, 06/28/07, 06/26/08, 08/27/09, 08/26/10, 08/25/11, 08/23/12, 08/22/13, 08/28/14, 08/27/15, 08/25/16, 08/25/17, 10/25/18 PAGE: 4 OF: 5
--	--

Lawrie TA, et al. Techniques for the interruption of tubal patency for female sterilization. *Cochrane Database Syst Rev* 2015 Sep 7;(9):CD003034.

Mao J, et al. Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study. *BMJ* 2015 Oct 13;351:h5162.

Sill, E., et al Analysis of surgeries performed after hysteroscopic sterilization as tabulated from 3,803 Essure patient experiences. *Obstet Gynecol Sci.* 2017 May; 60(3):296-302

Ukoha, et al. Post-Approval Clinical Studies of Essure: Quality of Evidence and Future Outlook [16G]. *Obstetrics & Gynecology*: May 2017

*World Health Organization. Medical eligibility criteria for contraceptive use. 5th edition 2015 [https://extranet.who.int/iris/restricted/bitstream/10665/181468/1/9789241549158_eng.pdf] accessed 9/5/18.

*key article

KEY WORDS:

Adiana® Permanent Contraception System, Essure®, Hysteroscopic tubal ligation, Sterilization, Tubal ligation.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Sterilization. Please refer to the following website for Medicare Members: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=13&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&Keyword=sterilization&KeywordLookUp=Title&KeywordSearchType=And&bc=gAAAABAAAA&>.