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 (e.g., Essure – note FDA black box label see Rationale) 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.

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.
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.

Although the US Food and Drug Administration (FDA) believes Essure is an appropriate option for the majority of women seeking a permanent form of birth control, in February 2016, they issued a requirement for a new, mandatory clinical study for Essure to determine if particular women were at heightened risk for potential complications; such as persistent pain, perforation of the uterus or fallopian tubes from device migration, abnormal bleeding, and allergy of hypersensitivity reactions. FDA Mandates Essure Black Box Warning, More Safety Studies - The FDA has also ordered Bayer, the company that manufactures Essure, to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment. Bayer will be required to develop and conduct a post-market study that will provide data to help the agency to better understand the risks associated with Essure and compare them to laparoscopic tubal ligation. This includes the rates of complications including unplanned pregnancy, pelvic pain and other symptoms, and surgery to remove the Essure device. The study will also evaluate how much these complications affect a patient’s quality of life. Additionally, it will collect information to identify reasons for why some patients don’t have a confirmation test to ensure that Essure has been properly placed three months after insertion. The FDA will use the results of this study to determine what, if any, further actions related to Essure are needed to protect public health.

In a review of the current data regarding effectiveness, complications, postoperative evaluation, and surgical interventions associated with Essure hysteroscopic sterilization. (Casey et al 2017) reported recent findings of hysteroscopic sterilization is a commonly performed procedure that is offered as a well-tolerated, effective, outpatient method of permanent sterilization. Over the past several years, concerns have been raised regarding correct placement and postoperative complications. This has led to statements by both the Food and Drug Administration (FDA) in October, 2016 and American Association of Gynecologic Laparoscopists in February, 2017, as a significant portion of women seek removal of these devices. A current black-box warning issued by the FDA in 2016 recommends discussion of the probabilities of rates or events of adverse outcomes associated with Essure placement.

In October 2015, a state population-based, observational cohort study of 8,048 patients undergoing hysteroscopic sterilization and 44,278 undergoing laparoscopic sterilization was published. The study took place in New York State
from 2005-2013. The objective of the study was to compare the safety and efficacy of hysteroscopic sterilization with the “Essure” device with laparoscopic. Outcomes measured were safety events within 30 days of the procedures, unintended pregnancies, and reoperations within one year of procedures. Mixed model accounting for hospital clustering was used to compare 30 day and 1 year outcomes, adjusting for patient characteristics and other confounders. Time to reoperation was evaluated using frailty model for time to event analysis. Patients undergoing hysteroscopic sterilization were older than those undergoing laparoscopic sterilization and were more likely to have a history of pelvic inflammatory disease (10.3% vs. 7.2%, P<0.01), major abdominal surgery (9.4% vs. 7.9%, P<0.01), and cesarean section (23.2% vs. 15.4%, P<0.01). At one year after surgery, hysteroscopic sterilization was not associated with a higher risk of unintended pregnancy (odds ratio 0.84 (95% CI 0.63 to 1.12)) but was associated with a substantially increased risk of reoperation (odds ratio 10.16) compared with laparoscopic sterilization. The authors concluded patients undergoing hysteroscopic sterilization have a similar risk of unintended pregnancy but a more than 10-fold higher risk of undergoing reoperation compared with patients undergoing laparoscopic sterilization and the benefits and risks of both procedures should be discussed with patients for informed decision making.

**REFERENCES:**
### SUBJECT: FEMALE STERILIZATION

**POLICY NUMBER:** 4.01.07  
**CATEGORY:** Contract Clarification

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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&P...