MEDICAL POLICY

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

• 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, 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 (e.g., Essure) 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.

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 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.
RATIONALE:
Female sterilization by ligature 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.

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.

In 2011, Anderson and Vancaille reported a prospective, single-arm, multicenter, international trial to evaluate the efficacy of the Adiana System for preventing pregnancy in women desiring permanent sterilization. The study was conducted at 16 sites in the United States, Australia, and Mexico. All patients, a total of 645 women, underwent attempted hysterectomy placement of the Adiana polymer matrix. There was a 95% bilateral matrix placement rate, 88.4% bilateral occlusion by hysterosalpingography at 12 weeks, and patients were monitored for pregnancy over 36 months. Complete 36-month data were available for 481 subjects. During the first year, 6 pregnancies were reported. Three were determined to be the result of misinterpretation of hysterosalpingography results. The remaining three were attributed to method failure, as were the three pregnancies during the second year. No additional pregnancies occurred in year three. The cumulative pregnancy prevention rates at 12, 24, and 36 months compare favorably with data from the Collaborative Review of Sterilization study and other published reports documenting efficacy of established permanent sterilization procedures. The authors concluded the data demonstrates the Adiana System is well tolerated with a durable safety profile and the efficacy for pregnancy prevention is similar to other permanent sterilization methods.

CODES:

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.

CPT: 58565  Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>58600</td>
<td>Ligation or transection of fallopian tube(s), abdominal or vaginal approach, unilateral or bilateral</td>
</tr>
<tr>
<td>58605</td>
<td>Ligation or transection of fallopian tube(s), abdominal or vaginal approach, postpartum, unilateral or bilateral, during same hospitalization (separate procedure)</td>
</tr>
<tr>
<td>58611</td>
<td>Ligation or transection of fallopian tube(s) when done at the time of cesarean delivery or intra-abdominal surgery (not a separate procedure)</td>
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<tr>
<td>58615</td>
<td>Occlusion of fallopian tube(s) by device (eg, band, clip, Falope ring) vaginal or suprapubic approach</td>
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<tr>
<td>58670</td>
<td>Laparoscopy, surgical; with fulguration of oviducts (with or without transection)</td>
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<tr>
<td>58671</td>
<td>with occlusion of oviducts by device (eg, band, clip, or Falope ring)</td>
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</tbody>
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**REFERENCES:**


*Proprietary Information of Excellus Health Plan, Inc.*


*key article

**KEY WORDS:**

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

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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&PolicyType=Final&s=New+York+-+Upstate&KeyWord=sterilization&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAABAAAAA&].