MEDICAL POLICY

Excellus

SUBJECT: FEMALE STERILIZATION	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
POLICY NUMBER: 4.01.07 CATEGORY: Contract Clarification	PAGE: 1 OF: 4

- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

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 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, are exempt from the requirement to cover contraceptive services.

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.

In 2011, Anderson and Vancaillie 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 hysteroscopic 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: 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.

CPT:	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)
	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)
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HCPCS:	A4264	Permanent implantable contraceptive intratubal occlusion device(s) and delivery system
ICD9:	V25.2	Sterilization
	V26.51	Tubal ligation status
ICD10:	Z30.2	Encounter for sterilization
	Z98.51	Tubal ligation status

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*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=gAAAABAAAAAA&