



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Hysteroscopic Tubal Sterilization ESSURE®

Effective Date 2/15/2009
Next Review Date 2/15/2011
Coverage Policy Number 0138

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INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA

Coverage Policy

Under many benefit plans, coverage for voluntary sterilization is subject to the terms, conditions and limitations of the applicable benefit plan's Family Planning Services benefit and schedule of copayments. Please refer to the applicable benefit plan document and schedules to determine benefit availability and the terms, conditions and limitations of coverage.

If coverage for voluntary sterilization is available under the applicable plan, the following conditions of coverage apply.

CIGNA covers hysteroscopic tubal sterilization (e.g., ESSURE®) for women who have completed childbearing and desire permanent sterilization.

General Background

Female sterilization is the number one contraceptive choice among women in the United States, with approximately eleven million women relying on bilateral tubal sterilization (BTS) for contraception, with an estimated 700,000 procedures performed every year. Sterilization is one of the most effective means of preventing unintended pregnancy. Female sterilization involves occlusion of the fallopian tube, obstructing sperm transport to the area of the tube where fertilization of the ovum occurs. The U.S. Collaborative Review of Sterilization (CREST), a landmark prospective, multicenter, observational study on the use of sterilization,

reported a 10-year failure rate for sterilization of 1.85% in 10,685 women. Although the CREST failure rates were higher than previously expected, the study confirmed that sterilization continues to be an extremely effective long-term contraceptive. Only the intrauterine device (IUD) and levonogestrel (Norplant) implant system (currently unavailable in the United States) have comparable long-term failure rates (Baill, 2003).

There are several methods that can be used for tubal sterilization; these involve the use of rings, clips, electrocautery, or ligation/segmental excision to interrupt the patency of the fallopian tubes surgically. Complications of female tubal sterilization include problems with anesthesia, hemorrhage, organ damage and mortality. Procedures that are performed surgically also require a brief period of convalescence (Sanfilippo, 2003; Tolaymat, 2006). In an effort to find a sterilization method that does not require the use of a surgical incision, and one that can provide safe and reliable permanent sterilization, a method of permanent birth control has been developed that involves the transcervical placement of an occlusive device that is directed into the fallopian tubes.

Transcervical Tubal Occlusion

Transcervical approaches to sterilization involve gaining access to the fallopian tubes through the cervix. A device or occlusive material (i.e., micro-insert) is then placed hysteroscopically or blindly to block each tube (ACOG, 2004). The ESSURE[®] System, which is currently approved for use, is comprised of the ESSURE micro-insert, a disposable delivery system and a disposable split introducer. According to the manufacturer, physicians must be trained in the handling and insertion techniques that are to be used with this device. The insertion of the ESSURE device can be performed with the patient under intravenous sedation or paracervical block; general anesthesia is not required. After implantation, the ESSURE device cannot be relied upon to provide birth control until complete occlusion is confirmed. Alternate methods of birth control must be utilized during this time. A hysterosalpingogram (HSG) must be performed at three months to confirm that bilateral fallopian tube occlusion has occurred; if the tube is still patent the HSG is repeated at six months.

Micro-insert implantation is considered an irreversible contraceptive technique. Removal of this device generally requires abdominal surgery under general anesthesia and may also require a hysterectomy. Since the device contains metal components, surgical procedures involving electrosurgery, radiofrequency, or microwave energy should not be performed near the implants. Patients should be made aware that the procedure is permanent, that there is no data to support its reversibility, and that there is a risk of ectopic pregnancy should the patient become pregnant.

U.S. Food and Drug Administration (FDA)

The ESSURE System (Conceptus, Inc.) was approved in 2002 after premarket approval application (PMA) by the FDA as a class III medical device. The FDA states that The ESSURE System is indicated for women who desire permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes. The FDA required Conceptus to conduct a five-year post approval studies of women who were included in their phase II, phase III and pivotal studies to determine the safety and effectiveness of the ESSURE system. The bilateral placement rate for newly trained physicians would also be evaluated (FDA, 2002). The results of these mandated post-approval studies led to the FDA granting the manufacturer approval in 2005 to modify the device labeling to include four- and five-year effectiveness results and other labeling changes.

Literature Review

Miño et al. (2007) prospectively evaluated the success rate of the ESSURE procedure as a method of sterilization in a cohort of 857 women. Satisfactory insertion was achieved in 845 women (98.6%) and follow-up evaluation was completed in all subjects. At three-month follow-up, the overall patient satisfaction after the ESSURE procedure was rated as very high by 94% of women (n=806) and high by 6% of the women (n=51). At this follow-up evaluation, four expulsions of the ESSURE device were reported. All were subsequently replaced at a second attempt. This study is limited by the lack of a control group and short-term follow-up. There was also no reporting on rates of pregnancy subsequent to insertion of the ESSURE system.

Duffy et al. (2005) compared patient satisfaction, discomfort, procedure time, success rate and adverse events of hysteroscopic ESSURE placement versus laparoscopic sterilization in a cohort controlled comparative study. The primary outcome measure was patient satisfaction. All women who underwent laparoscopic sterilization had the procedure successfully completed whereas the overall bilateral device placement rate for ESSURE was 81%. Adverse events reported within the ESSURE group included pain, perineal infection and prolonged (n=1), headaches (n=1), and vaginal spotting (n=1). Within the laparoscopic sterilization group the following adverse

events of urinary retention (n=1) wound infection (n=1) and abdominal pain (n=1) were reported. Patient satisfaction ratings were not significantly different between the two groups at the 90-day follow-up. The ESSURE group recovered at a faster pace than the laparoscopic patients; there was an 82% “good to excellent” tolerance of the ESSURE procedure versus the laparoscopic procedure, as more patients experienced post-procedure pain in the recovery room with the laparoscopic procedure.

National Institute for Health and Clinical Excellence (NICE, 2004) published guidance concerning hysteroscopic sterilization by tubal cannulation and placement of intrafallopian implants. They indicated that current evidence on the safety of hysteroscopic sterilization by tubal cannulation and placement of intrafallopian implants appears adequate. However, the evidence of the long-term efficacy does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.

Ubeda et al. (2004) conducted a prospective observational study to evaluate the results of hysteroscopic, intratubal, permanent birth control on 85 premenopausal women between July 2002 and July 2003. Successful placement of the ESSURE device was accomplished in 81 of the 85 patients (95%). At three months, only 75 (93%) of the 81 patients returned for their follow-up radiology films to document whether the device was correctly placed; after one year of post-procedure follow-up, no pregnancies have been reported. This study is small in size, nonrandomized and only provides one year of patient outcome data. Also, the patient outcomes reported do not include those lost to follow-up at the time of radiology review or when patients discontinued their use of alternative birth control measures.

Kerin et al. (2003) conducted a prospective, international multicenter trial with a cohort of 227 previously fertile women. Micro-insert placement was achieved in 88% of the women. Causes of the failure of bilateral device placement were anatomic, procedural or device-related including: tubal stenosis, occlusion, spasm, tortuous tubes, micro-insert perforation, deficient catheter performance and inability to cannulate due to unknown reasons. Of the 88% of women in whom placement was achieved, the correct placement was confirmed in 97% of cases at three months. After a 24-month follow-up, 98% of study participants rated their tolerance good to excellent. The length of time that women have been relying on the micro-insert for contraception ranges from 24 months to 36 months, with no reports of pregnancy. Limitations of this study include no long-term follow-up and a lack of comparison with other established methods of birth control.

Cooper et al. (2003) reported on 518 previously fertile women seeking sterilization. Micro-insert placement was attempted in 507. Insertion was not attempted in 11 women due to endometrium or uterine polyps blocking the ostia, inability to visualize the fallopian tubes for unspecified reasons, cervical stenosis, and inability to reach the ostia in obese women. Bilateral placement was achieved in 464 women. Adverse events included four perforations of the uterine wall, 14 expulsions, and three patients with proximal implant location. Three months after placement, correct placement and tubal occlusion were confirmed in 96% of the 464 cases. At final follow-up, no pregnancies were reported. The study is short in duration and lacks randomization and comparisons of established means of permanent sterilization versus this newly approved device.

Professional Societies/Organizations

American College of Obstetricians and Gynecologists (ACOG, 2003): ACOG published a practice bulletin concerning the benefits and risks of sterilization which states that short-term efficacy studies for transcervical sterilization using ESSURE suggests a rate equal to or greater than other tubal sterilization methods; however, long-term efficacy rates are not yet available (ACOG, 2003). This practice bulletin has not been updated since 2003.

Planned Parenthood (2008): Planned Parenthood lists ESSURE as a no-incision method for tubal sterilization. After two years of follow-up, ESSURE was found to be 99.8% effective at preventing pregnancy. Long-term side effects are not known. ESSURE offers some advantages over traditional methods of tubal sterilization which include the procedure being safer, the use of local versus general anesthesia, faster recovery time and no visible scarring. According to Planned Parenthood, some possible risks are:

- One or both of the coils may not be put in place correctly the first time. It may be necessary to have a second procedure.
- The coils may move out of place.
- The uterus may be injured during the insertion. This rare complication may require surgery.

- The coils may be damaged during other medical procedures.

Summary

There is a paucity of studies of comparing the ESSURE system to existing methods of permanent surgical sterilization (i.e., laparoscopic or minilaparotomy tubal ligation, tubal banding, tubal fulgeration). Studies conducted on the safety and effectiveness of this device have primarily focused on women receiving the ESSURE implant. As a result of data submitted to the U.S. Food and Drug Administration (FDA) by the manufacturer, patient follow-up has now shown device efficacy out to four and five years. Hysteroscopic tubal occlusion appears to be an effective nonsurgical alternative of sterilization for women who have completed childbearing and desire permanent sterilization.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT [®] * Codes	Description
58565	Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants.

ICD-9-CM Diagnosis Codes	Description
V25.2	Encounter for contraceptive management; sterilization

*Current Procedural Terminology (CPT[®]) © 2008 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	2/15/2007	0138	Hysteroscopic Tubal Sterilization ESSURE®
Great-West Healthcare	8/29/2006	04.235.03	Hysteroscopic Tubal Sterilization (ESSURE™)

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.