



CIGNA MEDICAL COVERAGE POLICY

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

Subject Hysteroscopic Tubal Sterilization

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Coverage Policy Number 0138

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[Infertility Services](#)

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer'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 customer'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 customer'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 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 ©2011 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[®], Adiana[®]) for a woman who has completed childbearing and desire permanent sterilization.

CIGNA does not cover hysteroscopic tubal sterilization for any other indication, including but not limited to hydrosalpinx, because it is considered experimental, investigational or unproven.

General Background

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. 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. 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). Hysteroscopic devices currently available for use include the Essure[®] System (Conceptus, Inc., San Carlos, CA) and the Adiana[®] Permanent Contraception System (Hologic, Inc., Marlborough MA). The Essure system is comprised of the micro-insert, a disposable delivery system and a disposable split introducer. Once the micro-insert coils are in place, scar tissue forms over the implants blocking each fallopian tube. The Adiana system utilizes radiofrequency energy to create small lesions in each fallopian tube for placement of the silicone micro-insert or matrix. Like the Essure system, tissue growth around the matrix results in tubal occlusion. Hysteroscopic sterilization does not require general anesthesia or incision, and can be performed in the outpatient setting. After implantation, the Essure and Adiana devices 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) is typically performed at three months to confirm that bilateral fallopian tube occlusion has occurred. A tubal perforation rate of 1% and an expulsion rate of 3% have been reported for the Essure system (Williams, 2008).

The use of hysteroscopic tubal occlusion is also being investigated for hydrosalpinx prior to in vitro fertilization (IVF)/intra-cytoplasmic sperm injection (ICSI). Hydrosalpinx is the buildup of fluid in a fallopian tube, usually at the end closest to the ovary, which can make it difficult for a woman to become pregnant. Salpingectomy, or surgical removal of the part of the fallopian tube that generates the fluid may improve fertility. Less frequently, a new opening in the part of the tube closest to the ovary may be surgically created. The U.S. Food and Drug Administration (FDA) has not approved hysteroscopic tubal sterilization devices for the treatment of hydrosalpinx.

U.S. Food and Drug Administration (FDA)

The Essure System was approved in November 2002 after premarket approval application (PMA) by the FDA as a class III medical device. On July 6, 2009, the Adiana device was approved by the FDA via the PMA process. According to the FDA, both the Essure and Adiana systems are indicated for women who desire permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes. Contraindications for use of the Essure system include the following:

- uncertainty about her desire to end fertility
- only one micro-insert can be placed (including patients with apparent contralateral proximal tubal occlusion and patients with a suspected unicornuate uterus)
- previous tubal ligation
- pregnancy or suspected pregnancy
- delivery or termination of a pregnancy less than six weeks before Essure micro- insert placement
- active or recent upper or lower pelvic infection
- known allergy to contrast media
- known hypersensitivity to nickel confirmed by skin test

The Adiana system should not be used in a woman who:

- is uncertain about her desire to end fertility
- has clinical evidence of an active pelvic infection or history of a recent pelvic infection
- has intra-uterine pathology which would prevent access to either tubal ostium or the intramural portion of either fallopian tube (such as large submucous fibroids, uterine adhesions, apparent uni- or bilateral proximal tubal occlusion, suspected unicornuate uterus, etc.)
- is pregnant or suspects pregnancy
- is currently less than three months since her last pregnancy
- has previously undergone a tubal ligation

- is currently taking immunosuppressive medications (e.g., steroids)
- has a known allergy to contrast media

The pivotal study for FDA approval was the Evaluation of the Adiana System for Sterilization Using Electrothermal Energy (EASE) trial. Of the 770 women enrolled in the EASE study, 645 underwent the procedure. A total of 570 went on to the one-year reliance period after successful HSG. At one-year follow-up, 86% of subjects were available for analysis. The cumulative pregnancy rates after one, two, and three years of reliance on the device were determined to be 1.1% (0.6-2.1), 1.6% (0.9-2.8), and 1.6% (0.9-2.8), respectively (FDA, 2009).

Literature Review

The evidence evaluating the safety and effectiveness of the Essure system consists primarily of cohort studies with a patient population range of 85–857 (Sinha, et al., 2007; Miño, et al., 2007; Duffy, et al., 2005; Ubeda, et al., 2004; Kerin, et al., 2003). Follow-up in some studies have extended to five years, with reported effectiveness rates of approximately 99%. A systematic review by Hurskainen et al. (2009) found that the evidence on efficacy and safety is mainly available from short follow-up case series but shows good efficacy and safety of the Essure system. Only a few small risks are associated with the procedure.

A systematic review by Palmer and Greenberg (2009) compared the Essure and the Adiana Systems and noted that the overall bilateral placement rates for both systems to be similar (94%-95%) with comparable rates of tubal occlusion after HSG. Data from the EASE study suggest that, although the Adiana system is over 98% effective, the 2-year cumulative failure rate is 1.82%.

Vancaillie et al. (2008) published one-year data from the EASE trial, a prospective, multicenter cohort study (n=770), in which the placement efficacy and reliability of the Adiana system for permanent contraception were evaluated. Inserts were placed bilaterally and fallopian tube occlusion was assessed with HSG at three months. Bilateral placement was achieved in 611 of 645 women (95 %). Bilateral occlusion was confirmed in 570 of 645 (88.4 %). The one-year pregnancy prevention rate was calculated to be 98.9%.

Although not robust, there is some evidence in the published peer-reviewed medical literature with short- and intermediate-term data to support the safety and effectiveness of hysteroscopic tubal sterilization using the Essure and Adiana devices. Long-term data is needed to confirm the current findings. There is insufficient evidence demonstrating the effectiveness of hysteroscopic tubal occlusion for hydrosalpinx prior to IVF.

Professional Societies/Organizations

A 2010 guidance from the National Institute for Health and Clinical Excellence (NICE) states that the current evidence on the safety of hysteroscopic sterilization by tubal cannulation and placement of intrafallopian implants appears adequate for the use of this procedure, if the normal arrangements for clinical governance and audit are in place. According to NICE, a number of different devices may be used for this procedure; these may include the use of adjunctive radiofrequency ablation (NICE, 2010).

In a 2010 Committee Opinion, the American College of Obstetricians and Gynecologists (ACOG) states that hysteroscopic tubal sterilization utilizing the two currently FDA-approved devices (i.e., Essure, Adiana) provides a welcome expansion of the contraceptive options available to women. ACOG emphasizes the need for HSG three months after hysteroscopic tubal sterilization to confirm tubal occlusion, in order to minimize the failure rates (ACOG, 2010).

The ACOG practice bulletin concerning the benefits and risks of sterilization states that short-term efficacy studies for transcervical sterilization using Essure suggest 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.

Summary

There is a paucity of studies of comparing hysteroscopic tubal sterilization 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 the U.S. Food and Drug Administration (FDA)-approved devices (i.e., Essure, Adiana) have primarily focused on women receiving the implants. As a result of data submitted to the FDA by the manufacturers, patient follow-up has now shown device efficacy out to four and five years for the

Essure system and three years for the Adiana system. Based on the available evidence primarily in the form of cohort studies, hysteroscopic tubal occlusion appears to be an effective and safe nonsurgical alternative of sterilization for women who have completed childbearing and desire permanent sterilization. There is insufficient evidence in the published peer-reviewed scientific literature to support the use of hysteroscopic tubal occlusion for hydrosalpinx prior to in vitro fertilization (IVF).

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

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
614.1	Chronic salpingitis and oophoritis
V26.51	Tubal ligation status
	All other codes

*Current Procedural Terminology (CPT[®]) © 2010 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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