Hysteroscopic Tubal Occlusion for Contraception
(Essure® and Adiana® Systems)

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:

This medical policy describes hysteroscopic tubal occlusion, a procedure that involves the insertion of a micro-insert into the ostium of each fallopian tube via a nonsurgical transvaginal approach. Unlike tubal ligation, there is no cutting, clipping, suturing, or burning of the fallopian tubes. The inserts do not contain or release hormones. The micro-inserts are designed to induce the formation of scar tissue that completely occludes the fallopian tubes. The goal of this procedure is to provide permanent contraception.

Hysteroscopic tubal occlusion is an alternative for women who want permanent, highly effective birth control but don’t want an abdominal surgical procedure. Since the procedure is not reversible, women must be sure they do not want any more children.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

Hysteroscopic tubal occlusion using micro-inserts (e.g., Essure® birth control system, Adiana® Permanent Contraception System) may be considered MEDICALLY NECESSARY for women who desire permanent birth control by bilateral occlusion of the fallopian tubes.

A hysterosalpingogram is considered MEDICALLY NECESSARY three months after the procedure to verify insert placement and tubal occlusion. A second hysterosalpingogram may be performed again at 6 months if the initial hysterosalpingogram did not show occlusion.

CLINICAL CONSIDERATIONS:

- Individuals are at least 21 years of age at the time consent is obtained. Consent must be informed and voluntarily signed by the member to be sterilized. The member is mentally competent, not pregnant, and not institutionalized.

- Patient with hysteroscopic tubal occlusion procedure will need to keep using a birth control method until a hysterosalpingogram test 3 months after the procedure to make sure it worked.

CONTRAINDICATIONS:

Hysteroscopic tubal sterilization is contraindicated in any woman with any of the following conditions:

- Proximal tubal occlusion
- Unicornuate uterus
- Has previously undergone a tubal ligation
- Is uncertain about her desire to end fertility
- Active or recent upper or lower pelvic infection
- Delivery or termination of a pregnancy less than 6 weeks before occlusion device placement
- Known allergy to contrast media
- For the Essure® System: Known hypersensitivity to nickel confirmed by skin test
- For the Adiana® System: Currently taking immunosuppressive medications (e.g., steroids) is a relative contraindication
- Pregnancy or suspected pregnancy
BACKGROUND:

There are more than 100 million women worldwide who rely on tubal sterilization for contraception. In the United States, this figure is approximately 11 million women, or one fourth of all women of reproductive age. For women who desire to end their fertility permanently, the standard treatment is minimally invasive, transabdominal surgical sterilization, usually minilaparotomy or laparoscopy. Minilaparotomy involves a 3- to 4-cm incision in the abdomen, whereas laparoscopy requires insertion of a laparoscope through a small subumbilical incision and insertion of other instruments through additional incisions. In these procedures, the fallopian tubes are tied, sealed with a clip, or cauterized to effect permanent sterilization. To avoid the discomfort and potential complications associated with surgery (e.g., anesthesia-related, infection, hemorrhage, and organ damage), various nonsurgical transcervical methods of occlusion of the fallopian tubes have been or are being developed and tested. Of these, the Essure® and the Adiana® permanent tubal occlusion contraception systems have FDA approval. The primary advantages of these systems over other techniques of female sterilization are that the Essure® and Adiana® Systems are non-incisional and sterilization can be performed without general anesthesia.

The Essure® Permanent Birth Control System (Conceptus Inc.):

In the Essure® procedure, a flexible titanium micro-insert is placed into the interstitial portion of each fallopian tube under hysteroscopic guidance. The insert is packaged as a single-use delivery system and consists of an inner coil of stainless steel and polyethylene terephthalate (PET) fibers and an outer coil of nickel-titanium (nitinol). PET fibers were chosen because of their known success in causing tissue ingrowth into medical devices in other procedures, such as arterial grafts. For patients with known nickel sensitivity by skin testing, placement of the device is contraindicated. The device is placed in the proximal fallopian tube in the wound down state and then deployed to an expanded state that anchors the insert along a 3-cm segment of the tube. After placement, the PET fibers stimulate a benign tissue response that elicits the invasion of macrophages, fibroblasts, foreign body giant cells, and plasma cells. Within several weeks, the fibrotic ingrowth around the device results in complete tubal occlusion. In the United States, tubal occlusion and proper positioning must be confirmed 12 weeks following microinsert placement by hysterosalpingogram (HSG). Outside the United States, a pelvic x-ray is required at 12 weeks postprocedure to confirm microinsert placement. Backup contraception must be used until proper position and bilateral tubal occlusion are confirmed by HSG.

The Adiana® Permanent Contraception System (Hologic, Inc.):

The Adiana® sterilization method is a combination of controlled thermal damage to the lining of the fallopian tube followed by insertion of a non-absorbable biocompatible silicone elastomer matrix within the tubal lumen. Under hysteroscopic guidance, a delivery catheter is introduced into the tubal ostium. Once placement inside the intramural section of the fallopian tube is confirmed, the distal tip of the catheter delivers radiofrequency (RF) energy for a period of 1 minute, causing a 5-mm lesion within the fallopian tube. Following thermal injury, the 3.5-mm silicone matrix is deployed within the lesion and the catheter and hysteroscope are removed. Over the next few weeks, occlusion is achieved by fibroblast ingrowth into the matrix, which serves as permanent scaffolding and allows for “space-filling.” Occlusion of tubes must be assessed by HSG three months after device placement in both the United States and Europe. Although visible via ultrasound, the Adiana® matrix is not visible via x-ray or HSG.

Main Points:

- Transcervical sterilization is a less invasive hysteroscopic procedure. Along with the decreased potential
for complications, is its ease of performance with minimal anesthesia in the operating room or office.

- In the Essure® procedure, a microinsert is placed into the interstitial portion of each fallopian tube under hysteroscopic guidance. Benign tissue ingrowth around the device results in complete tubal occlusion. The Adiana® sterilization method is a combination of controlled thermal damage to the lining of the fallopian tube followed by insertion of a nonabsorbable biocompatible silicone elastomer matrix within the tubal lumen. Occlusion is achieved by fibroblast ingrowth into the matrix.

- Essure’s bilateral placement rate is 94.6%. Adiana’s bilateral placement rate is 94%; after a second procedure, 95% achieve bilateral placement.

- Hysteroscopic tubal occlusion with Essure® represents the most effective of all female or male sterilization techniques, whereas the Adiana® failure rate is higher than all methods except for spring clip ligation.

- Both Essure® and Adiana® reduced procedural discomfort and increased patient satisfaction when compared with laparoscopic tubal ligation.

- The outpatient office-based nature of transcervical female sterilization gives this method a very favorable cost profile as compared with other methods.

- Both systems are well tolerated with low rates of adverse events.

- The effectiveness data for both technologies are based on proper placement and confirmation of tubal occlusion. These endpoints should be evaluated in 3 stages: (1) confirming proper device placement during the procedure, (2) confirming tubal occlusion at 90 days, and (3) understanding the risk of pregnancy for women who do not follow-up.

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**REGULATORY STATUS:**

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):**
   
   Hysteroscopic Tubal Occlusion for Permanent Contraception devices are regulated by the FDA as a Class III devices.

   - **The Essure® Permanent Birth Control System (Conceptus Inc.):** Approved via the FDA Premarket Approval process on November 2002. This system was designed to provide a non-incisional alternative to women seeking permanent contraception. Using a hysteroscopic approach under local anesthesia, one Essure® micro-insert, which resembles a tiny spring, is placed in the proximal section of each fallopian tube lumen. The most recent FDA decision regarding Essure® concerned approval for modification of the labeling to indicate 4- and 5-year effectiveness rates, issued on July 12, 2005 (FDA, 2006).

   - **The Adiana® Permanent Contraception System (Hologic, Inc.):** Approved via the FDA Premarket Approval process on July 6, 2009. The FDA approved the Adiana® Permanent Contraception System for women who desire non-reversible permanent birth control.

   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.

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):
CMS has no national policy specifically regarding Medicare coverage of hysteroscopic tubal occlusion (CMS, 2006a). However, the CMS National Coverage Determination (NCD) for sterilization states that sterilization procedures of any kind are not covered “if the stated reason for these procedures is sterilization” (CMS, 2006b). It is explained that payment for any sterilization procedure may be made only when “sterilization is a necessary part of the treatment of an illness or injury, e.g., removal of a uterus because of a tumor, removal of diseased ovaries (bilateral oophorectomy), or bilateral orchidectomy in a case of cancer of the prostate,” and when pathological evidence of the necessity to perform a sterilization procedure to treat an illness or injury is present. The NCD also states that “sterilization of a mentally retarded beneficiary is covered if it is a necessary part of the treatment of an illness or injury” and “sterilization that is performed because a physician believes another pregnancy would endanger the overall general health of the woman is not considered to be reasonable and necessary for the diagnosis or treatment of illness or injury. The same conclusion would apply where the sterilization is performed only as a measure to prevent the possible development of, or effect on, a mental condition should the individual become pregnant.” In addition, Medicare does not cover sterilization of a mentally retarded person where the purpose is to prevent conception rather than treat an illness or injury (CMS, 2006b).

3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):
Provider Manual - Reproductive Health/OB-GYN - Sterilization (Revised: 03-08-2013)

COVERED SERVICES
MFPP covers voluntary sterilization. All sterilization procedures must follow MHCP sterilization requirements. The Sterilization Consent Form must be completed in order for MHCP to reimburse providers for performing sterilization procedures. This requirement applies to all MHCP recipients (MA and MinnesotaCare) except Emergency Medical Assistance (EH).

The following sterilization services are covered:
- Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; NOS
- Anesthesia, tubal ligation/transection
- Hysteroscopy, surgical with bilateral fallopian tube cannulation to induce occlusion
- Laparoscopy, surgical; with fulguration of oviducts (with or without transection)
- Laparoscopy, surgical; with occlusion of oviducts by device (e.g., bland, clip, or Falope ring)
- Ligation or transection of fallopian tube(s), abdominal or vaginal approach
- Occlusion of fallopian tube(s) by device (e.g., band, clip, Falope ring) vaginal or suprapubic approach
- Vasectomy, unilateral or bilateral (separate procedure), including postop semen exam

The following criteria must be met in order for a sterilization to be covered by MHCP:
- The recipient must be:
  - At least 21 years of age at the time the consent form is signed
  - Mentally competent
  - Not institutionalized
Voluntarily signing the Sterilization Consent Form (MHCP will not accept a consent form signed by a guardian, conservator, or anyone other than the individual to be sterilized.)

- Consent form signature, date, and timeline

NON-COVERED SERVICES
MHCP does not cover:

- Reversal of voluntary sterilization
- Sterilization of a mentally incompetent recipient
- Sterilization of a recipient institutionalized voluntarily, civilly committed, or court ordered, in a(n):
  - Intermediate care facilities for people with developmental disabilities or related condition (ICF/DD-RC)
  - Regional treatment centers that are not institutions for mental disease (RTC, not IMD)
  - Regional treatment centers that are institutions for mental disease (RTC-IMD)
  - Institutions for mental disease (IMD)
  - Correctional facilities (county or non-county)
  - Chemical dependency rehabilitation programs
  - Residential facilities for mentally ill persons
- Sterilization of anyone who consented to sterilization and was under age 21 years at the time of consent
- Sterilization without the recipient's informed consent, including sterilization in which a person has given consent for the recipient, including court-ordered sterilization of a mentally incompetent or institutionalized recipient
- Sterilizations consented to by recipients:
  - In labor or childbirth
  - Seeking to obtain or obtaining an abortion
  - Under the influence of alcohol or other substances that affect the recipient's state of awareness
  - In a situation that the provider believes that the recipient is unable to give informed consent

DEFINITIONS

_Institutionalized Individual:_ An individual who is involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental health or other facility for the care and treatment of mental illness, or confined under a voluntary commitment in a mental health or other facility for the care and treatment of mental illness.

_Mentally Incompetent Individual:_ An individual who is declared mentally incompetent by a federal, state, or local court of competent jurisdiction for any purpose, unless the individual has been declared competent for purposes which include the ability to consent to sterilization.

Note: A recipient who has a legal guardian is considered a mentally incompetent individual.

4. **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES:**

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.

“All Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.”


CLINICAL EVIDENCE:

SUMMARY:
Transcervical tubal sterilization has expanded the repertoire of permanent contraceptive options for women. In addition, as compared with incisional methods of sterilization, the risks are markedly reduced. The Essure® procedure has proved to be well tolerated, safe, and effective. To date, there are approximately 300 publications in the literature on these systems, thus adding to the body of knowledge regarding this technique.

Main Points:

- Transcervical sterilization is a less invasive hysteroscopic procedure. Along with the decreased potential for complications, its ease of performance with minimal anesthesia in the operating room or the office.
- In the Essure® procedure, a microinsert is placed into the interstitial portion of each fallopian tube under hysteroscopic guidance. Benign tissue ingrowth around the device results in complete tubal occlusion. The Adiana® sterilization method is a combination of controlled thermal damage to the lining of the fallopian tube followed by insertion of a nonabsorbable biocompatible silicone elastomer matrix within the tubal lumen. Occlusion is achieved by fibroblast ingrowth into the matrix.
- Essure®'s bilateral placement rate is 94.6%. Adiana's bilateral placement rate is 94%; after a second procedure 95% achieve bilateral placement.
- Hysteroscopic tubal occlusion with Essure® represents the most effective of all female or male sterilization techniques, whereas the Adiana® failure rate is higher than all methods except for spring clip ligation.
- Both Essure® and Adiana® reduced procedural discomfort and increased patient satisfaction when compared with laparoscopic tubal ligation.
- The outpatient office-based nature of transcervical female sterilization gives this method a very favorable cost profile as compared with other methods.
- Both systems are well tolerated with low rates of adverse events.
- The effectiveness data for both technologies are based on proper placement and confirmation of tubal occlusion. These endpoints should be evaluated in 3 stages: (1) confirming proper device placement during the procedure, (2) confirming tubal occlusion at 90 days, and (3) understanding the risk of pregnancy for women who do not follow-up.
APPLICABLE CODES:

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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<tr>
<td>A4264</td>
<td>Permanent implantable contraceptive intratubal occlusion device(s) and delivery system</td>
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<td>Encounter for sterilization</td>
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<td>58340</td>
<td>Catheterization and introduction of saline or contrast material for saline infusion sonohysterography or hysterosalpingography</td>
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<td>58565</td>
<td>Hysteroscopy; surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants</td>
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CPT® is a registered trademark of the American Medical Association.

REFERENCES:


29. McSwain H, Shaw C, Hall LD. Placement of the Essure® permanent birth control device with


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