Clinical Policy Title: Hysteroscopic tubal occlusion for permanent female sterilization

Clinical Policy Number: 12.02.07

Effective Date: February 1, 2017
Initial Review Date: November 16, 2016
Most Recent Review Date: November 16, 2016
Next Review Date: November 2017

Related policies:
None.

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Prestige Health Choice when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Prestige Health Choice’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of hysteroscopic tubal occlusion for permanent female sterilization to be clinically proven and, therefore, medically necessary for women desirous of permanent birth control by bilateral occlusion of the fallopian tubes.

Prestige Health Choice considers a hysterosalpingogram to be clinically proven and, therefore, medically necessary when performed no earlier than three months post-insertion of the occlusive device to verify correct placement and complete tubal occlusion.

Limitations:

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website can be accessed at
http://ahca.myflorida.com/Medicaid/.

Prestige Health Choice considers hysteroscopic tubal occlusion/manipulation for all other indications (e.g., hydrosalpinx, in vitro fertilization) to be investigational and, therefore, not medically necessary.

All other uses of hysteroscopic tubal occlusion/manipulation are considered investigational and, therefore, not medically necessary.

**Alternative covered services:**

Primary care and specialty physician (including surgical) evaluation and management.

**Background**

Permanent sterilization (i.e., tubal ligation) is a widely used approach to achieve female contraception. Over a decade ago a non-incisional technique of female sterilization became available for bilateral tubal occlusion via hysteroscopic placement of metal (i.e., nickel) inserts at the utero-tubal junction. The procedure, known as “hysteroscopic sterilization” (HS) takes advantage of the body’s natural scar-forming properties to permanently obstruct the small fallopian tubes through which spermatozoa travel to fertilize the egg in the ovary, and has several advantages over standard laparoscopic tubal ligation:

- It eliminates the need for abdominal access.
- It reduces overall cost.
- It requires minimal anesthesia.

Both Essure® and Adiana® HS contraception systems were proven efficacious and safe by relatively short-term clinical trial data, and both received initial approval by the Food and Drug Administration (FDA) in 2002 and 2009 respectively. Currently, Essure® is the only commercially available HS device used in clinical practice, since the Adiana® system was removed from the market for commercial, non-health reasons (i.e., infringement of patent) by the manufacturer in 2012.

**Searches**

Prestige Health Choice searched PubMed and the databases of:

- UK National Health Services Center for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on October 11, 2016. Searched terms were: "hysteroscopic sterilization (MeSH)" "tubal occlusion (MeSH)" and “contraception.”
We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews.**

- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Depes (2016) evaluated the results of early tubal occlusions performed by hysteroscopy (Essure®) in 38 patients, mean age 34.5 years, who had on average 3 pregnancies and 2.7 deliveries per woman. The HS procedure required only a mean time of anesthesia of 4 minutes and 50 seconds. Based on the analogical visual scale, average pain reported was three; and 55.3 percent of women did not report pain at all after the procedure. After 3 months, 89.5 percent of patients reported they were “very satisfied” with the HS method. Followup radiographs of the pelvis showed 92.1 percent of the devices implanted were satisfactorily placed. One case of spontaneous unilateral expulsion occurred. At four years of follow-up there were no reported contraceptive failures from the HS method.

Carney (2016) evaluated women’s preferences in the choice of HS versus laparoscopic sterilization (LS) in the U.S. in both the commercial and Medicaid marketplaces. Medical insurance claims from women aged 15–49 years were retrospectively examined during the time period of January 1, 2003 to December 31, 2012. Among commercially insured women, those who had a sterilization procedure during 2008–2012 were more likely to undergo HS (odds ratio: 7.1, P<0.001) than those who had a sterilization procedure during 2003–2007. Among Medicaid-insured women, the likelihood of having HS versus LS increased 3.3-fold (P<0.001) in years 2009–2011 compared to years 2006–2008. Among both populations, older age, obesity, and the use of oral contraceptives within the previous 12 months were associated with having HS versus LS.

The U.S. Food and Drug Administration (FDA) in September 2015 convened an advisory committee to discuss Essure® safety and effectiveness and to assess the existing medical literature and adverse event reports regarding the device. The FDA ordered the manufacturer (Bayer) to conduct a postmarket surveillance study and to obtain more data about Essure®'s benefits and risks. The FDA acted in the wake of allegations of clinical trial misconduct, notably that clinical trial participants’ medical records were altered to reflect more favorable data about participants’ experiences, and that the sponsor violated laws that relate to the manufacturing and marketing of Essure®. The FDA acknowledged that less than one percent of data pertaining to pain, bleeding, device placement/movement and pregnancy were changed during the clinical trials. The FDA reiterated that decision-making advice was not solely limited to the Essure® device, but was reported with other sterilization methods as well. The FDA also agreed that hysteroscopic sterilization is an important option for women who are not good candidates
for laparoscopic or general surgery and who are well informed of the potential risks of the device. At the same time, patients with a known hypersensitivity to metal, autoimmune disease, history of pelvic inflammatory disease, and those with a history of abnormal uterine bleeding may be less suitable candidates for the Essure® system.

The FDA (2016) conducted a search of the Manufacturer and User Facility Device Experience (MAUDE) database from Nov. 4, 2002, Essure®'s approval date, through December 31, 2015. During this period the FDA received 9,900 medical device reports related to Essure®. The majority of reports received since 2013 were voluntary reports, mostly from women who received Essure® implants. The most frequently reported patient problems during this period were pain/abdominal pain (6989), heavier menses/menstrual irregularities (3210), headache (2990), fatigue (2159), and weight fluctuations (2088). Most of the reports received listed multiple patient problems in each report. The most frequent device problems reported were patient-device incompatibility (2016) (e.g., possible nickel allergy), migration of the device or device component (854), device operating differently than expected (490), device breakage (429), device difficult to remove (280), malposition of the device (199), and device difficult to insert (187). Thirty-two reports were coded by the submitter as “death.” Six of these were incorrectly coded, as there was no indication of death in the report. Of the remaining 26, six relate to four adult deaths; 18 reports relate to 15 incidences of pregnancy loss; and two reports related to two incidents of a death of an infant after live birth. There were 631 reports of pregnancies in patients with Essure®. Of these, 150 were reported to result in a live birth; 204 did not indicate whether the pregnancy resulted in a live birth or pregnancy loss; and 294 resulted in pregnancy loss. Among the 294 reports of women who experienced a pregnancy loss, 96 were reported as ectopic pregnancies; 43 were reported as elective terminations of pregnancies, and 155 were other pregnancy losses. The FDA concluded that although there is evidence of complications, as there are with many medical devices, overall usage results did not demonstrate any new safety problems or an increased incidence of problems since the time of device approval.

The FDA also sought to determine what long-term complications may be associated with Essure® more than five years after placement, because the post-approval study evaluated safety and effectiveness only up to five years. There was no conclusive evidence in the literature indicating any new or more widespread complications definitely associated with Essure® occurring more than five years after device placement. The FDA concluded that Essure® does not pose an increased risk to public health and that its benefits continue to outweigh the risks.

Mao (2015) compared the safety and efficacy of HS with the Essure® device to LS in a large, all-inclusive, New York state cohort of 8048 patients and 44,278 patients respectively between 2005 and 2013. There was a significant increase in the use of hysteroscopic procedures during this period, while use of LS decreased. Patients undergoing HS were older than those undergoing LS and were more likely to have a history of pelvic inflammatory disease (10.3 percent v 7.2 percent, P<0.01), major abdominal surgery (9.4 percent v 7.9 percent, P<0.01), and cesarean section (23.2 percent v 15.4 percent, P<0.01). At one year after surgery, HS was not associated with a higher risk of unintended pregnancy (odds ratio 0.84 (95 percent CI 0.63 to 1.12) but was associated with a substantially increased risk of reoperation (odds
ratio 10.16 (7.47 to 13.81) compared with laparoscopic sterilization. The authors concluded that patients undergoing HS have a similar risk of unintended pregnancy but a more than 10-fold higher risk of undergoing reoperation compared with patients undergoing LS.

McMartin (2013) in a systematic review of 22 studies compared HS with tubal ligation for permanent female sterilization to determine the effectiveness and safety of hysteroscopic tubal sterilization. Only 1 (n = 93) of the 22 studies compared HS to laparoscopic tubal ligation. Overall, HS was associated with lower pregnancy rates and lower complication rates compared to tubal ligation. No deaths were reported for HS. However, the authors acknowledged that a lack of long-term follow-up for HS and a paucity of studies that directly compare the two procedures were limitations of their assessment. In addition, optimal placement of the microinsert at the time of hysteroscopy varied among studies.

Sills (2015) retrospectively examined by survey 103 unplanned pregnancies following HS. Mean patient age was 29.5±4.6 years. Peak pregnancy incidence was reported at 10 months after HS, although <3 percent of unplanned pregnancies occurred within the first three months following HS. Some unplanned pregnancies were reported up to 7 years later. Mean (±SD) interval between HS and pregnancy was 19.6±14.9 (range, 2 to 84) months. Patients age ≥30 years reported conception after HS somewhat sooner than younger patients, although the differences in time to pregnancy were not significant (P=0.24 and 0.09, respectively). The recommended post-HS hysterosalpingogram (to confirm proper insert placement and bilateral tubal occlusion) was obtained by 66 percent (68/103) of respondents.

The Toronto Health Economic and Technology Assessment Collaborative (THETA, 2013) studied the effectiveness of hysteroscopic tubal sterilization compared with laparoscopic tubal ligation for permanent female sterilization. Cost-utility analyses (studies that report outcomes in terms of costs and quality-adjusted life-years) were prioritized for inclusion, and when these were not available, cost-effectiveness, cost-benefit, and cost-consequence analyses were considered as alternative data sources. A retrospective chart review from Canada found that HS was $111 less costly than LS; a prospective activity-based cost management study from Italy reported that it was €337 less costly than LS; and the results of an American decision model showed that HS was $1,178 less costly than LS. The authors concluded that, although the HS device was more expensive due to the cost of the microinserts, HS cost overall was less than LS overall due to the shorter recovery time required.

The Affordable Care Act (ACA) of 2010 mandates that plans in the health insurance marketplace must cover contraceptive methods and counseling for all women, as prescribed by a health care provider. Plans must cover these services without charging a copayment or coinsurance when provided by an in-network provider.

Covered contraceptive methods include:

- Barrier methods, like diaphragms and sponges.
- Hormonal methods, like birth control pills and vaginal rings.
- Implanted devices, like intrauterine devices (IUDs).
- Emergency contraception, like Plan B® and ella®.
- Sterilization procedures.
- Patient education and counseling.

Health plans sponsored by certain exempt religious employers, like churches and other houses of worship, are not required to cover contraceptive methods and counseling. Some non-profit religious organizations — like non-profit religious hospitals and institutions of higher education that certify they have religious objections to contraceptive coverage — are not required to contract, arrange, pay, or refer for contraceptive coverage.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Depes (2016)</td>
<td><strong>Key points:</strong></td>
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</table>
| Initial experience with hysteroscopic tubal occlusion (Essure®) | - Evaluated the results of early tubal occlusions performed by hysteroscopy (Essure®) in 38 patients, mean age 34.5 years, who had on average 3 pregnancies and 2.7 deliveries per woman.  
- The HS procedure required only a mean time of anesthesia of 4 minutes and 50 seconds.  
- Based on the analogical visual scale, average pain reported was three; and 55.3 percent of women did not report pain at all after the procedure.  
- After 3 months, 89.5% of patients reported they were “very satisfied” with the HS method.  
- Followup radiographs of the pelvis showed 92.1% of the devices implanted were satisfactorily placed.  
- One case of spontaneous unilateral expulsion occurred. At four years of follow-up there were no reported contraceptive failures from the HS method. |
| Carney (2016)     | **Key points:**                                                                                   |
| Temporal trend in the use of hysteroscopic versus laparoscopic sterilization and the characteristics of commercially insured and Medicaid-insured females in the US who have had the procedures | - Evaluated womens’ preferences in the choice of HS versus LS in the U.S. in both the commercial and Medicaid marketplaces.  
- Medical insurance claims from women aged 15–49 years were retrospectively examined during the time period of January 1, 2003 to December 31, 2012.  
- Among commercially insured women, those who had a sterilization procedure during 2008–2012 were more likely to undergo HS (odds ratio: 7.1, P<0.001) than those who had a sterilization procedure during 2003–2007.  
- Among Medicaid-insured women, the likelihood of having HS versus LS increased 3.3-fold (P<0.001) in years 2009–2011 compared to years 2006–2008.  
- Among both populations, older age, obesity, and the use of oral contraceptives within the previous 12 months were associated with having HS versus LS. |
| FDA (2016)        | **Key points:**                                                                                   |
| Essure® Permanent Birth Control | - The FDA conducted a search of the MAUDE database from Nov. 4, 2002, Essure®'s approval date, through December 31, 2015.  
- During this period the FDA received 9,900 medical device reports related to Essure®. |
- The majority of reports received since 2013 were voluntary reports, mostly from women who received Essure® implants.
- The most frequently reported patient problems during this period were pain/abdominal pain (6989), heavier menses/menstrual irregularities (3210), headache (2990), fatigue (2159), and weight fluctuations (2088).
- Most of the reports received listed multiple patient problems in each report.
- The most frequent device problems reported were patient-device incompatibility (2016) (e.g., possible nickel allergy), migration of the device or device component (854), device operating differently than expected (490), device breakage (429), device difficult to remove (280), malposition of the device (199), and device difficult to insert (187).
- Thirty-two reports were coded by the submitter as “death.” Six of these were incorrectly coded, as there was no indication of death in the report. Of the remaining 26, six relate to four adult deaths; 18 reports relate to 15 incidences of pregnancy loss; and two reports related to two incidents of a death of an infant after live birth.
- There were 631 reports of pregnancies in patients with Essure®. Of these, 150 were reported to result in a live birth; 204 did not indicate whether the pregnancy resulted in a live birth or pregnancy loss; and 294 resulted in pregnancy loss.
- Among the 294 reports of women who experienced a pregnancy loss, 96 were reported as ectopic pregnancies; 43 were reported as elective terminations of pregnancies, and 155 were other pregnancy losses.
- The FDA concluded that although there is evidence of complications, as there are with many medical devices, overall usage results did not demonstrate any new safety problems or an increased incidence of problems since the time of device approval.
- The FDA also sought to determine what long-term complications may be associated with Essure® more than five years after placement, because the post-approval study evaluated safety and effectiveness only up to five years.
- There was no conclusive evidence in the literature indicating any new or more widespread complications definitely associated with Essure® occurring more than five years after device placement.
- The FDA concluded that Essure® does not pose an increased risk to public health and that its benefits continue to outweigh the risks.

<table>
<thead>
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<th>FDA (2015)</th>
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<td>Brief Summary of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee Meeting</td>
<td>- FDA in September 2015 convened an advisory committee to discuss Essure® safety and effectiveness and to assess the existing medical literature and adverse event reports regarding the device.</td>
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<td>- The FDA ordered the manufacturer (Bayer) to conduct a postmarket surveillance study and to obtain more data about Essure®’s benefits and risks.</td>
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are not good candidates for laparoscopic or general surgery and who are well informed of the potential risks of the device.
- At the same time, patients with a known hypersensitivity to metal, autoimmune disease, history of pelvic inflammatory disease, and those with a history of abnormal uterine bleeding may be less suitable candidates for the Essure® system.

<table>
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<th>Mao (2015)</th>
<th>Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study</th>
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| **Key points:** | - Compared the safety and efficacy of HS with the Essure® device to LS in a large, all-inclusive, New York state cohort of 8048 patients and 44,278 patients respectively between 2005 and 2013.  
- There was a significant increase in the use of hysteroscopic procedures during this period, while use of LS decreased.  
- Patients undergoing HS were older than those undergoing LS 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, HS 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 (7.47 to 13.81) compared with laparoscopic sterilization.  
- The authors concluded that patients undergoing HS have a similar risk of unintended pregnancy but a more than 10-fold higher risk of undergoing reoperation compared with patients undergoing LS. |

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<tr>
<th>McMartin (2013)</th>
<th>Hysteroscopic Tubal Sterilization: An Evidence-Based Analysis</th>
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</thead>
</table>
| **Key points:** | - Systematic review of 22 studies compared HS with tubal ligation for permanent female sterilization to determine the effectiveness and safety of hysteroscopic tubal sterilization.  
- Only 1 (\( n = 93 \)) of the 22 studies compared HS to laparoscopic tubal ligation. Overall, HS was associated with lower pregnancy rates and lower complication rates compared to tubal ligation.  
- No deaths were reported for HS. However, the authors acknowledged that a lack of long-term follow-up for HS and a paucity of studies that directly compare the two procedures were limitations of their assessment.  
- Optimal placement of the microinsert at the time of hysteroscopy varied among studies. |

<table>
<thead>
<tr>
<th>Sills (2015)</th>
<th>Contraceptive failure after hysteroscopic sterilization: Analysis of clinical and demographic data from 103 unplanned pregnancies</th>
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| **Key points:** | - Retrospectively survey of 103 unplanned pregnancies following HS.  
- Mean patient age was 29.5±4.6 years.  
- Peak pregnancy incidence was reported at 10 months after HS, although <3 percent of unplanned pregnancies occurred within the first three months following HS. Some unplanned pregnancies were reported up to 7 years later.  
- Mean (±SD) interval between HS and pregnancy was 19.6±14.9 (range, 2 to 84) months.  
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- The recommended post-HS hysterosalpingogram (to confirm proper placement and bilateral tubal occlusion) was obtained by 66 percent (68/103) of respondents. |
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<th>THETA Collaborative (2013)</th>
<th>Key points:</th>
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</table>
| Hysteroscopic Tubal Sterilization: A Health Economic Literature Review | - Studied the effectiveness of HS compared with LS for permanent female sterilization.  
- Cost-utility analyses (studies that report outcomes in terms of costs and quality-adjusted life-years) were prioritized for inclusion, and when these were not available, cost-effectiveness, cost-benefit, and cost-consequence analyses were considered as alternative data sources.  
- A retrospective chart review from Canada found that HS was $111 less costly than LS; a prospective activity-based cost management study from Italy reported that it was €337 less costly than LS; and the results of an American decision model showed that HS was $1,178 less costly than LS.  
- The authors concluded that, although the HS device was more expensive due to the cost of the microinserts, HS cost overall was less than LS overall due to the shorter recovery time required. |

<table>
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<tr>
<th>ACA (2010)</th>
<th>Key points:</th>
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| Birth control benefits | - ACA mandates that plans in the health insurance marketplace must cover contraceptive methods and counseling for all women, as prescribed by a health care provider.  
- Plans must cover these services without charging a copayment or coinsurance when provided by an in-network provider.  
- Covered contraceptive methods include:  
  - Barrier methods, like diaphragms and sponges  
  - Hormonal methods, like birth control pills and vaginal rings  
  - Implanted devices, like intrauterine devices (IUDs)  
  - Emergency contraception, like Plan B® and ella®  
  - Sterilization procedures  
  - Patient education and counseling  
- Health plans sponsored by certain exempt religious employers, like churches and other houses of worship, are not required to cover contraceptive methods and counseling. Some non-profit religious organizations — like non-profit religious hospitals and institutions of higher education that certify they have religious objections to contraceptive coverage — are not required to contract, arrange, pay, or refer for contraceptive coverage. |

**Glossary**

**Tubal occlusion** — A widely used approach to achieve female contraception involving the occlusion of the bilateral fallopian tubes to obstruct and prevent the male spermatozoa from reaching the ovarian egg.

**Hysteroscopic sterilization** — A non-incisional technique of female sterilization by bilateral fallopian tubal occlusion via hysteroscopic placement of metal (i.e., nickel) inserts at the utero-tubal junction.

**Essure®** — The only commercially available HS device used in clinical practice in the U.S.

**Adiana®** — An HS device removed from the market for commercial, non-health reasons (i.e.,
infringement of patent) by the manufacturer in 2012.

References
Professional society guidelines/other:


Peer-reviewed references:


CMS National Coverage Determination (NCDs):
No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**
No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill in accordance with those manuals.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>58565</td>
<td>Hysteroscopy, surgery; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants</td>
<td></td>
</tr>
<tr>
<td>74740</td>
<td>Hysterosalpingography, radiological supervision and interpretation</td>
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<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>Z30.2</td>
<td>Encounter for sterilization</td>
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<tr>
<th>HCPCS Level II</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>A4264</td>
<td>Permanent implantable contraceptive intratubal occlusion device(s) and delivery system</td>
<td></td>
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