



# PROVIDER *bulletin*

February 22, 2010

Dear Provider,

Attached are the reimbursement criteria for Tubal Occlusion (Essure) that was recommended by the Kern Health Systems Physician Advisory Committee, and approved by the KHS Board of Directors. These criteria will be used by KHS Medical Directors and Claims department to determine reimbursement. KHS Medical Directors will retrospectively monitor and manage the utilization of this new procedure for overuse, underuse or misuse trends. If you have any questions, please contact our Provider Relations Department at (661)664-5146.

Sincerely,

Jake Hall  
Provider Relations Supervisor  
Kern Health Systems



## Kern Health Systems Criteria

**Department: UM**

**Category: Hysteroscopic Tubal Sterilization**

**Subject: Tubal Occlusion Sterilization Policy (Essure)**

All candidates for tubal sterilization must have a properly completed sterilization form PM 330 and the required waiting period must be completed, i.e. 30 days from completion and dating of the form, but not more than 180 days.

The Essure Micro-Insert System is the first FDA approved hysteroscopic approach to tubal sterilization. It became a Medi-Cal benefit in May 2008, retroactive to January 1, 2008. The primary advantages of the Essure System (and other micro insert systems) over other techniques of female sterilization are that no incisions are required and sterilization can be performed without general anesthesia. **Therefore, a facility fee will not be reimbursed.**

However, its disadvantages are:

1. the need for an alternative form of birth control for 3, to 6 months or beyond;
2. an extra HSG at 3 and possibly another one at 6 months;
3. a 14% primary failure rate (one in seven).

Using a hysteroscopic approach, a micro insert is placed in the proximal section of each fallopian tube lumen. The micro-insert expands upon release, acutely anchoring itself in the fallopian tube. The micro-insert anchors the device and occludes the fallopian tube, resulting in sterilization. This process takes approximately three months and requires the patient to use an additional form of birth control for those three months. After the three month waiting period, a hysterosalpingogram must be done to confirm that the tubes are occluded. This is a fluoroscopic x-ray procedure that requires dye to be injected into the uterine cavity and fallopian tubes to confirm tubal closure. If one or both of the tubes remains open, the procedure may be repeated one time by the same surgeon. In the initial studies, the procedure was successful 86% of the time, that is, it failed 14% of the time on the initial attempt. The procedure was 90% successful on the second attempt. Third attempts are not considered covered benefits of the Health Plan.

According to the FDA approved labeling, these systems are **contraindicated** in any woman who:

- Is uncertain about her desire to end fertility; or



- Can have only one micro-insert placed (including members with apparent contralateral proximal tubal occlusion and members with a suspected unicornuate uterus); *or*,
- Has previously undergone a tubal ligation

They are also **contraindicated** for women with any of the following conditions:

- Pregnancy or suspected pregnancy; *or*
- Delivery or termination of a pregnancy less than 6 weeks before Essure micro-insert placement; *or*,
- Active or recent upper or lower pelvic infection; *or*
- Known allergy to contrast media or known hypersensitivity to nickel (for the Essure system).

A micaroinert system will not be authorized for women who are candidates for a tubal ligation. Patients who are not candidates for tubal ligation include:

- Women who cannot undergo laparoscopic surgery
- Women who are poor candidates for a general anesthetic.

The provider seeking treatment authorization for placement of a micro-insert system must also attest to the following:

- 1) He/She has been trained and certified in the system.
- 2) He/She has provided full informed consent regarding this procedure and alternative methods of permanent sterilization, including vasectomy.
- 3) Documentation of a thorough hysteroscopic evaluation of the uterine cavity.
- 4) The patient has none of the above listed contraindications to the procedure, *and*
- 5) Present a treatment plan that includes:
  - i. The specific contraceptive to be used in the interval from placement of the micro-insert until confirmation of tubal occlusion by HSG
  - ii. Scheduling of the HSG
  - iii. Specific advice that once the micro-insert is placed, it cannot be retrieved other than by major surgery, i.e. laparotomy and uterine tubal excision.
  - iv. Reasonable assurance that the patient will not require steroid therapy during the period of time between the placement of the micro-insert and the HSG.

The above policy is based on but not limited to the following references:



1. Conceptus, Inc. Essure Microinsert System. Prescribing information. Document No. CC-0366. San Carlos, C: Conceptus; July 16, 2004. Available at <http://www.essure.com/static/hcp/prescribing.pdf>.
2. State of California sterilization form PM 330
3. Essure, page 3 Medi-Cal Update – Billing and Policy May 2008 GM 3
4. ACOG Practice Bulletin Number 46, September 2003, Benefits and Risks of Sterilization

Created By: Dr. Graves 8/25/09

Annotated by Dr. Brooks 1/13/10, 2/3/10

