**Medical Policy**

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<th>Section</th>
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**Issue**

12:2013

**Disclaimer**

Our medical policies are designed for informational purposes only and are not an authorization, or an explanation of benefits, or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

**Description**

Permanent forms of elective sterilization include vasectomy or tubal ligation. Tubal ligation is a surgical procedure, typically performed laparoscopically, but requiring general anesthesia. Recently, a hysteroscopic approach to permanent sterilization has been developed. The Essure System involves the insertion of micro-inserts bilaterally into the fallopian tubes. The resulting scarring permanently occludes the fallopian tubes, rendering the patient infertile. To confirm occlusion, the patient typically undergoes a hysterosalpingogram (HSG) at 3 months; if the tube(s) are still patent, the HSG is repeated at 6 months. Patients must rely on alternate forms of birth control until complete occlusion is confirmed.

The U.S. Food and Drug Administration (FDA)-labeled indication for the Essure System states, “The Essure System is indicated for women who desire permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes.”

**Policy**

Bilateral occlusion of the fallopian tubes using hysteroscopic placement of micro-inserts may be considered **medically necessary** as a technique for permanent sterilization.
Policy Guidelines

There is a specific CPT describing the placement of the micro-inserts. 58565; Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants.

Three months after placement of the micro-inserts, patients will undergo a separate hysterosalpinogram (CPT code 74740) to confirm occlusion of the fallopian tubes.

Rationale

Data regarding the safety and effectiveness of the Essure System is based on information contained in the package insert and 1 published clinical trial. (1,2) The pivotal trial that formed the basis of the FDA approval included 518 women who underwent placement of the micro-inserts. Bilateral micro-inserts were successfully placed in 86% of patients, and in 90% of patients with 2 attempts. All patients were evaluated with a hysterosalpingogram (HSG) at 3 months, which was repeated at 6 months if the initial HSG did not document occlusion. The effectiveness rate after 2 years of follow-up was 99.8%. Adverse events that prevented reliance on the device for contraception included failure to place 2 micro-inserts at the first procedure (14%), initial tubal patency (3.5%), expulsion (2.2%), perforation (1.5%), or other unsatisfactory device location (0.6%).

2004 Update

A literature search was performed for the period of 2003 through November of 2003. No additional published studies were identified that would prompt reconsideration of the policy statement; therefore the policy statement is unchanged. The pivotal trial data presented to the FDA has now been published in the peer-reviewed literature. (3) Another case series of 85 patients reported procedural success in 95% of patients. (4)

References:

1. www.essure.com

<table>
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<tr>
<th>Codes</th>
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<tbody>
<tr>
<td>CPT</td>
<td>58565</td>
<td>Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants</td>
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<tr>
<td></td>
<td>74740</td>
<td>Hysterosalpingography, radiologic supervision and interpretation</td>
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<td>ICD-9</td>
<td>V25.2</td>
<td>Admission for interruption of fallopian tubes or vas deferens</td>
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Sterilization, Essure Device