BACKGROUND

Hysteroscopic tubal sterilization is accomplished by placement of implants within the fallopian tubes. This procedure, performed only by trained providers, is done in the outpatient setting. Using a hysteroscopic approach, one Essure System is placed in the proximal section of each fallopian tube lumen. The Essure System expands upon release, acutely anchoring itself in the fallopian tube and subsequently elicits a benign tissue response. Tissue in-growth into the Essure System anchors the device and occludes the fallopian tube, resulting in sterilization.

The Health Care Authority (HCA) has reviewed available research on available device systems to achieve tubal sterilization, as has a CHPW Medical Director. At this time, only the Essure System has been investigated sufficiently in long-term studies to demonstrate adequate safety and efficacy. The Essure System was approved by the Food and Drug Administration in 2002. Several subsequent revisions to the system have also been approved.

Approval of the Essure System by the FDA was based on the results of a Phase III clinical trial involving 518 sexually active reproductive-age women who underwent a placement procedure. The Essure System was reported to be 98% effective in preventing pregnancy after 2 years follow-up.

Available data shows that this procedure is at least as safe and effective as other current sterilization procedures, or better.
REQUIRED REVIEW AND APPROVALS

Hysteroscopic tubal sterilization procedures require prior authorization by the Community Health Plan Medical Director or his/her designee.

POLICY:

For Commercial and Medicare Advantage Members:
CHPW uses MCG

For WA Apple Health Members:
CHPW uses the WA Health Care Authority Medicaid Provider Guide April 1, 2016 criteria and requirements for hysteroscopic tubal sterilization procedures.
Link: https://www.hca.wa.gov/assets/billers-and-providers/physician-related-services-bi-20170401.pdf
(checked 04/10/2017)
Search “Sterilization Supplemental Billing Guide” and select the most recent billing guide.

SPECIAL CONSIDERATIONS FOR WA APPLE HEALTH MEMBERS:

All criteria and requirements in this Provider Guide MUST be met before CHPW will authorize a hysteroscopic tubal sterilization procedure. CHPW requires that providers performing hysteroscopic sterilization with the Essure device be registered with HCA as an Approved Provider in order to receive prior authorization to perform procedures for CHP WA APPLE HEALTH members.

Link to list of HCA-approved hysteroscopic sterilization providers:
(checked 04/10/2017)
INDICATIONS/Criteria

CHPW considers hysteroscopic tubal sterilization/transcervical sterilization (e.g., the Essure System) medically necessary for women who desire permanent birth control by bilateral occlusion of the fallopian tubes.

CHPW considers hysteroscopic tubal sterilization/transcervical sterilization (e.g., the Essure System) experimental and investigational for all other indications (e.g., hydrosalpinx).

CONTRAINDICATIONS

Hysteroscopic tubal sterilization is also contraindicated for women with any of the following conditions:

- Active or recent upper or lower pelvic infection; or
- Delivery or termination of a pregnancy less than 6 weeks before occlusion device placement; or
- Known allergy to contrast media or known hypersensitivity to nickel confirmed by skin test; or
- Pregnancy or suspected pregnancy.

LIMITATIONS/EXCLUSIONS

Please refer to a product line’s certificate of coverage for benefit limitations and exclusions for these services:

<table>
<thead>
<tr>
<th>PRODUCT LINE</th>
<th>LINK TO CERTIFICATE OF COVERAGE</th>
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<tr>
<td>WASHINGTON HEALTH PROGRAM</td>
<td><a href="http://chpw.org/our-plans/apple-health/">http://chpw.org/our-plans/apple-health/</a></td>
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CITATIONS & REFERENCES

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<tr>
<th>CFR</th>
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**Contract Citation**
- WAH: http://chpw.org/our-plans/apple-health/
- HBE

**Other Requirements**

**NCQA Elements**
- UM 2

**References**
Clinical Coverage Criteria


REVISION HISTORY

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<thead>
<tr>
<th>Revision Date</th>
<th>Revision Description</th>
<th>Revision Made By</th>
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<tr>
<td>01/19/2011</td>
<td>Original draft</td>
<td>Lucy Sutphen, MD, FACP</td>
</tr>
<tr>
<td>01/26/2011</td>
<td>Approval</td>
<td>MMLT</td>
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<tr>
<td>12/14/2011</td>
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<td>11/28/2012</td>
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<tr>
<td>04/08/2014</td>
<td>Added details of and links to requirements under WA APPLE HEALTH. Removed restrictions that might limit member choice of provider for MEDICARE ADVANTAGE and COMMERCIAL Lines of Business.</td>
<td>MMLT</td>
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## Clinical Coverage Criteria

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<tr>
<td>04/01/2016</td>
<td>Updated links, references and citations, including addition AH FIMC as separate line of business with its own benefit book</td>
<td>Kate Brostoff MD</td>
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<td>04/06/2016</td>
<td>Approval</td>
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<tr>
<td>04/10/2017</td>
<td>Updated links, removed references to Adiana which is off the market, corrected name of Essure from Essure micro-implant to Essure System.</td>
<td>LuAnn Chen, MD</td>
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<tr>
<td>04/12/2017</td>
<td>Minor Editing</td>
<td>Cyndi Stilson, RN</td>
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