Clinical Policy: Essure Removal

Reference Number: PA.CP.MP.131
Effective Date: 01/18
Last Review Date: 05/28/2020

Coding Implications
Revision Log

Description
This policy describes the medical necessity requirements for the removal of Essure®, a permanent birth control method that involves the bilateral placement of coils into the fallopian tubes which results in the development of scar tissue and occlusion of the fallopian tubes.

Policy/Criteria
I. It is the policy of Pennsylvania Health and Wellness® that the removal of Essure is **medically necessary** when meeting all of the following:
- A. Member is having symptoms related to the device such as abdominal/pelvic pain or heavy/irregular menses not related to other gynecologic pathologies, device migration, or nickel allergy/hypersensitivity;
- B. Performed by a gynecologist or surgeon experienced in removing the device;
- C. Radiologic evaluation to determine the device location;
- D. One of the following procedures:
  1. Hysteroscopy if ≤ 7 weeks post-placement;
  2. Laparoscopy or laparotomy for one of the following:
     a. Linear salpingotomy, salpingostomy, or salpingo-oophorectomy;
     b. Cornual resection and repair;
     c. Removal of devices that have migrated from the fallopian tubes.

Background
Essure is a form of permanent birth control that can be performed in an office setting and does not require incisions or general anesthesia. It involves the placement of spring-like devices into the proximal section of each fallopian tube via hysteroscopy. Over the next three months, scar tissue forms around the Essure coils facilitating insert retention and pregnancy prevention. The build-up of tissue creates a barrier to block sperm from reaching the eggs, preventing pregnancy.

Over the past several years, a growing number of adverse events have been reported to the FDA (Food and Drug Administration) associated with the use of Essure. Frequently reported adverse events include pain/abdominal pain, menstrual irregularities, headache, fatigue, device migration, allergy/hypersensitivity reaction, and weight fluctuations. Because of these reported adverse events, there has been an increase in the number of women seeking removal of the Essure device.

In April 2018 the FDA restricted sales of Essure to only doctors and healthcare facilities who use the FDA-approved "Patient-Doctor Discussion Checklist – Acceptance of Risk and Informed Decision Acknowledgement." Essure will no longer be available in the United States after December 31, 2018. It was removed from international markets in 2017.

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted

CPT® Codes	Description
58555	Hysteroscopy, diagnostic (separate procedure)
58562	Hysteroscopy, surgical; with removal of impacted foreign body
58579	Unlisted hysteroscopy procedure, uterus
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58673	Laparoscopy, surgical; with salpingostomy (salpingoneostomy)
58700	Salpingectomy, complete or partial, unilateral or bilateral (separate procedure)
58770	Salpingostomy (salpingoneostomy)

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
N92.0-N92.6	Excessive, frequent and irregular menstruation
R10.0-R10.84	Abdominal and pelvic pain
R21	Rash and other nonspecific skin erruption
T56.891*	Toxic effect of other metals, accidental (unintentional)
T83.428*	Displacement of other prosthetic devices, implants and grafts of genital tract

*7th digit required

Reviews, Revisions, and Approvals	Date	Approval Date
Annual Review. Updated background.	12/18	03/19
Codes reviewed. References reviewed and updated.	05/2020	08/2020

References

1. Bayer HealthCare LLC. Essure, permanent birth control, instructions for use. 2002
2. FDA Review Document. Review of the Essure system for hysteroscopic sterilization. Prepared for the September 24, 2015 meeting of the Obstetrics and Gynecology Devices Advisory Panel Center for Devices and Radiological Health (CDRH) United States Food and Drug Administration. Accessed 10/9/2019 at: https://wayback.archive-it.org/7993/20170112001932/http:/www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/ucm463457.htm
3. FDA Activities. Essure. Accessed 10/9/2019 at: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm

4. FDA Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization Guidance for Industry and Food and Drug Administration Staff. October 31, 2016. Accessed 10/9/2019 at: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM488020.pdf
5. Greenberg J, Yunker AC. Hysteroscopic sterilization. In: UpToDate, Waltham, MA. Abrams SA (Ed). Accessed 10/9/2019.
6. Clark NV, Rademaker D, Mushinski AA, et al. Essure Removal for the Treatment of Device-Attributed Symptoms: An Expanded Case Series and Follow-up Survey. J Minim Invasive Gynecol. 2017 Sep - Oct;24(6):971-976.
7. Casey J, Cedo-Cintron L, Pearce J, Yunker A. Current techniques and outcomes in hysteroscopic sterilization: current evidence, considerations, and complications with hysteroscopic sterilization micro inserts. Curr Opin Obstet Gynecol. 2017 Aug;29(4):218-224.
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