

Clinical Policy: Essure Removal

Reference Number: PA.CP.MP.131

Effective Date: 01/18

Coding Implications Date of Last Revision: 10/22/2022 **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

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from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT [®]	Description	
Codes		
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	Description
Code	
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

^{*7&}lt;sup>th</sup> digit required

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Annual Review. Updated background.	12/18	03/19
Codes reviewed. References reviewed and updated.	05/2020	8/6/2020
Annual Review. Codes & references reviewed and updated as	8/31/2021	
necessary.		
Annual review. References reviewed and updated. Reviewed by	9/22/2022	
Specialist. Changed "Last Review Date" in the header to "Date of Last		
Review" and "Date" in revision log to "Revision Date."		

References

- 1. Bayer HealthCare LLC. Essure, permanent birth control, instructions for use. https://labeling.bayerhealthcare.com/html/products/pi/essure_ifu.pdf?r=1. Accessed September 21, 2021.
- 2. U.S. Food and Drug Administration, Center for Devices and Radiological Health. The Essure System for Permanent Sterilization. Meeting of the Obstetrics and Gynecology Devices Advisory Panel. https://www.federalregister.gov/documents/2015/07/22/2015-

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<u>17985/obstetrics-and-gynecology-devices-panel-of-the-medical-devices-advisory-committee-notice-of-meeting</u> Published September 24, 2015. Accessed September 21, 2021.

- 3. FDA Activities. Essure. https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm. Accessed September 21, 2021.
- 4. FDA Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization, Guidance for Industry and Food and Drug Administration Staff. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/labeling-permanent-hysteroscopically-placed-tubal-implants-intended-sterilization. Published October 2016. Accessed September 28, 2021.
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- 6. Clark NV, Rademaker D, Mushinski AA, Ajao MO, Cohen SL, Einarsson JI. Essure Removal for the Treatment of Device-Attributed Symptoms: An Expanded Case Series and Follow-up Survey. *J Minim Invasive Gynecol*. 2017;24(6):971-976. doi:10.1016/j.jmig.2017.05.015.
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- 9. Bhagavath B, Lindheim S. Removal of Essure: TMTOWTDI. *Fertil Steril*. 2020;114(1):81. doi:10.1016/j.fertnstert.2020.04.035