Clinical Policy: Essure Removal

Reference Number: CP.MP.131
Last Review Date: 10/19

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation® 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 report 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

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 eruption
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
Policy developed. Specialist reviewed	11/16	11/16
Reworded criteria in I.D. per specialist suggestion to include laparoscopy or laparotomy for one of the following: salpingotomy, salpingostomy or salingo-oophorectomy, as well as corneal resection and repair, and removal of devices that have migrated from the fallopian tubes.	12/16	
References reviewed and updated	11/17	11/17
Updated background	10/18	10/18
Codes reviewed. References reviewed and updated.	10/19	10/19

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 10/9/19 at: https://wayback.archive-it.org/7993/20170112001932/http:/www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/ucm463457.htm
3. FDA Activities. Essure. Accessed 10/9/19 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 10/9/19 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.
8. Chudnoff SG, Nichols JE Jr, Levie M. Hysteroscopic Essure Inserts for Permanent Contraception: Extended Follow-Up Results of a Phase III Multicenter International Study. Minim Invasive Gynecol. 2015;22(6):951. Epub 2015 Apr 24.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.