ESSURE® REIMBURSEMENT GUIDE: A RESOURCE FOR CODING

INDICATION

Essure® is indicated for women who desire permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes.

IMPORTANT SAFETY INFORMATION

WARNING: Some patients implanted with the Essure System for Permanent Birth Control have experienced and/or reported adverse events, including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the Essure System for Permanent Birth Control during discussion of the benefits and risks of the device.

ESSURE PROCEDURE CODING

Current Procedural Terminology (CPT®) Fourth Edition* Codes

CPT-4 is a listing of descriptive terms and codes for reporting services and procedures performed by healthcare providers. The following code may be used to report procedures associated with Essure:

Product/Service	CPT Code	Code Description
Essure procedure	58565	Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants

Healthcare Common Procedure Coding System (HCPCS) codes

Level II HCPCS codes are published and updated annually by CMS. These alphanumeric codes are used to report drugs, supplies, and services.

Please note that Medicare does not allow for separate reporting and billing of the permanent implantable contraception. Private payers and Medicaid will make their own determination on whether or not to use the HCPCS code. Please confirm with your payer that A4264 is allowed for billing and will be paid. The HCPCS code used by facilities and some Medicaid plans to report Essure is:

Product/Service	HCPCS Code	Code Description
Essure	A4264	Permanent implantable contraceptive intratubal occlusion device(s) and delivery system

Diagnosis Codes

The International Classification of Diseases, 10th revision, Clinical Modification (ICD-10-CM) codes are used to classify diagnoses and conditions, and support medical necessity for specific procedures and services. They are used to indicate the reason for performing a given procedure and may be used by payers to determine coverage. The following ICD-10-CM codes may be applicable to women who receive Essure:

ICD-10-CM Code	Code Description
Z30.2	Encounter for sterilization

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PLEASE SEE THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, THROUGHOUT THIS GUIDE.

ESSURE® CONFIRMATION TEST CODING

Current Procedural Terminology (CPT®) Fourth Edition* Codes
The following codes may be used to report procedures associated with Essure.

Product/Service	CPT Code	Code Description
TVU	76830	Ultrasound: Transvaginal
Modified HSG	58340	Catheterization and introduction of saline or contrast material for saline infusion sonohysterography (SIS) or HSG
Modified HSG, interpretation and supervision	74740	HSG, radiologic supervision and interpretation
Modified HSG, interpretation	74740-26	HSG, radiologic supervision and interpretation, professional component only
Modified HSG, supervision	74740-TC	HSG, radiologic supervision and interpretation, technical component only

ICD-10-CM Diagnosis Codes
For many payers, the following codes may be used to identify the Essure Confirmation Test as a preventive service:

ICD-10-CM Code	Code Description	Recognized by†:
Z30.8	Other specified contraceptive management	Most payers
Z98.51	Tubal ligation status	UHC
Z30.42	Encounter for surveillance of injectable contraceptive	Cigna
Z30.2	Encounter for sterilization	Cigna

†Subject to change.

IMPORTANT SAFETY INFORMATION (continued)

IMPORTANT

- **Caution:** Federal law restricts this device to sale by or on the order of a physician. Device to be used only by physicians who are knowledgeable hysteroscopists; have read and understood the Instructions for Use and Physician Training Manual; and have successfully completed the Essure training program, including preceptoring in placement until competency is established, typically 5 cases.
- The sale and distribution of this device are restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Bayer.

Contraindications

Essure is contraindicated in patients who are uncertain about ending fertility, can have only one insert placed (including contralateral proximal tubal occlusion or suspected unicornuate uterus), have a known abnormal uterine cavity that makes visualization of the tubal ostia impossible, and/or abnormal tubal anatomy or previous tubal ligation (including failed ligation), are pregnant or suspect pregnancy, delivered or terminated a pregnancy less than 6 weeks prior to the Essure procedure, have an active upper or lower genital tract infection, have unexplained vaginal bleeding, have a gynecological malignancy, or have a known allergy to contrast media.

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MODIFIERS

Preventive Services

CPT Modifier 33 is applicable for the identification of preventive services without cost sharing and may be added to the following codes as shown below.

Product/Service	CPT Code	Code Description
Essure procedure	58565-33	Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants
Modified HSG	58340-33	Catheterization and introduction of saline or contrast material for SIS or HSG
TVU	76830-33	Ultrasound, transvaginal

Note: Not all commercial payers will require the use of Modifier 33. Some will automatically process Essure® and the Essure Confirmation Test without patient cost sharing.

Incomplete Procedures

In some cases, the Essure procedure is initiated but cannot be completed. In these cases, it may be appropriate to bill within Modifier 52 or 53 as described below.

Product/Service	CPT Code	Code Description
Essure procedure, reduced services	58565-52	This modifier is used to report a service or procedure that is partially reduced or eliminated at the physician's election. An example of the correct use of Modifier 52 would be a failure of placement on one side, resulting in unilateral placement of Essure.
Essure procedure, discontinued	58565-53	This modifier is used to report a procedure that is discontinued by the physician because of extenuating circumstances. Modifier 53 can only be used after anesthesia has been administered. An example of the correct use of Modifier 53 would be an Essure procedure being discontinued because the ostium of the fallopian tube is not visible.

IMPORTANT SAFETY INFORMATION (continued)

General Warnings

- The Essure procedure should be considered irreversible.
- Pain (acute or persistent) of varying intensity and length of time may occur following Essure placement. This is also more likely to occur in individuals with a history of pain. If device removal is indicated, this will require surgery.
- Patients with known hypersensitivity to nickel, titanium, platinum, stainless steel, and PET (polyethylene terephthalate) fiber or any of the components of the Essure system may experience an allergic reaction to the insert. In addition, some patients may develop an allergy to nickel or other components of the insert following placement. Symptoms reported for this device that may be associated with an allergic reaction include hives, urticaria, rash, angioedema, facial edema and pruritis. Patients should be counseled on the materials contained in the insert prior to the Essure procedure. Currently there is no test that reliably predicts who may develop a hypersensitivity reaction to the materials contained in the insert.
- Patients on immunosuppressive therapy may experience delay or failure of the necessary tissue ingrowth for tubal occlusion. For these patients, physicians must use the modified HSG as the Essure Confirmation Test. Transvaginal ultrasound (TVU) should not be used as the Essure Confirmation Test, as TVU cannot confirm tubal occlusion.

LOCAL CODING

Some state Medicaid programs may require the use of state-specific coding. Providers should research Medicaid coding guidelines on a state-specific basis.

Place of Service (POS)

The location where the clinician provides the medical service is referred to as the place of service (POS). All providers must include a POS code when submitting claims. The POS codes that pertain to the Essure procedure are as follows:

- POS #11 = office setting (PO)
- POS #22 = outpatient hospital (HOPD)
- POS #24 = ambulatory surgical center (ASC)

IMPORTANT SAFETY INFORMATION (continued)

Pregnancy Risk

- Pregnancies, including ectopic pregnancies, have been reported among women who have undergone the Essure procedure.
- The patient must use alternative contraception until a satisfactory Essure Confirmation Test is documented. If the Essure inserts are not properly placed or are not in a satisfactory location, then the patient should be advised to not rely on Essure and to use alternative contraception.
- Counsel the patient on the need for the Essure Confirmation Test, the options for the confirmation test including their risks and benefits, and the possibility that the Essure Confirmation Test may be unsatisfactory.
- Effectiveness rates for the Essure procedure are based on patients who had bilateral placement and a satisfactory Essure Confirmation Test.

Procedure Warnings

- Never attempt to advance Essure insert(s) against excessive resistance. If a perforation occurs or is suspected, discontinue procedure and monitor the patient for signs and symptoms of possible complications related to perforation which may include unusual post-operative pain.
- To reduce the risk of hypervolemia, terminate procedure if distension fluid deficit exceeds 1500cc or total hysteroscopic procedure time exceeds 20 minutes. Excess fluid deficit may signal uterine or tubal perforation. If noted, discontinue procedure and evaluate patient for possible perforation.
- Do not attempt hysteroscopic Essure insert removal during the placement procedure unless 18 or more trailing coils are seen inside the uterine cavity due to risk of a fractured insert, fallopian tube perforation, or other injury.
- DO NOT perform the Essure procedure concomitantly with endometrial ablation.

MRI Information

The Essure insert was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05.

Adverse Events

The most common (≥10%) adverse events resulting from the placement procedure were cramping, pain, and nausea/vomiting. The most common adverse events (≥3%) in the first year of reliance were back pain, abdominal pain, and dyspareunia.

This product does not protect against HIV infection or other sexually transmitted diseases.

Prescription Only

For additional information, please see the Instructions for Use available at EssureMD.com or speak to your Bayer Sales Consultant.