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

**Important Safety Information About Essure®**

**Prescription Only**

**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.

**Who should not use Essure**
- Essure is contraindicated in patients who are uncertain about ending fertility, can have only one insert placed (including contralateral proximal tubal occlusion or suspected unicorneate uterus), have previously undergone a tubal ligation, are pregnant or suspect pregnancy, delivered or terminated a pregnancy less than 6 weeks prior to the Essure procedure, have an active or recent upper or lower pelvic infection, or have a known allergy to contrast media.

**PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ON PAGE 2.**
Important Safety Information About Essure® (continued)

Pregnancy Considerations

• The Essure procedure should be considered irreversible. Patients should not rely on Essure inserts for contraception until an Essure Confirmation Test [modified hysterosalpingogram (HSG)] demonstrates bilateral tubal occlusion and satisfactory location of inserts.

• Effectiveness rates for the Essure procedure are based on patients who had bilateral placement. If Essure inserts cannot be placed bilaterally, then the patient should not rely on Essure inserts for contraception.

• Effects, including risks, of Essure inserts on in vitro fertilization (IVF) have not been evaluated.

• Pregnancies (including ectopic pregnancies) have been reported among women with Essure inserts in place. Some of these pregnancies were due to patient non-compliance or incorrect clinician interpretation of the Essure Confirmation Test (modified HSG).

Procedural Considerations

• Patients undergoing immunosuppressive therapy (e.g. systemic corticosteroids or chemotherapy) are discouraged from undergoing the Essure procedure.

• Uterine or fallopian tube anomalies may make it difficult to place Essure inserts.

• Perform the Essure procedure during early proliferative phase of the menstrual cycle. Terminate procedure if distension fluid deficit exceeds 1500cc or hysteroscopic time exceeds 20 minutes as it may signal uterine or tubal perforation. Never attempt to advance Essure insert(s) against excessive resistance. If tubal or uterine perforation occurs or is suspected, discontinue procedure and work-up patient for possible complications related to perforation, including hypervolemia. 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 fractured insert, fallopian tube perforation or other injury.

• DO NOT perform the Essure procedure concomitantly with endometrial ablation. Avoid electrosurgery on uterine cornua and proximal fallopian tubes without visualizing inserts.

• Some Essure patients have reported pelvic pain that may be device related. If device removal is indicated, this will require surgery.

Nickel Allergy

Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. In addition, some patients may develop an allergy to nickel if this device is implanted. Typical allergy symptoms reported for this device include rash, pruritus, and hives.

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.

Clinical Trial Experience

• Safety and effectiveness of Essure is not established in patients under 21 or over 45 years old, nor in patients who delivered or terminated a pregnancy less than 8-12 weeks before procedure. Women undergoing sterilization at a younger age are at greater risk of regretting their decision.

• 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.
CODING

Accurate diagnosis, procedure, and product coding are essential to help ensure prompt claims processing and reimbursement.

Using the correct and specific codes is critical. Most payers, public and private, utilize coding systems developed by the Centers for Medicare & Medicaid Services (CMS).

Healthcare providers are responsible for selecting the appropriate codes used in filing a claim. Codes should be based on the patient’s diagnosis and the items and services furnished by the provider.

GLOBAL FEE

There are multiple necessary services done by a healthcare provider when performing a procedure. These services are said to be billed/paid “globally”—sometimes referred to as the global/surgical package.

The global/surgical package also includes a global period: a set number of days during the post-operative period. The global period is usually 90 days for major procedures and 0-10 days for minor procedures. Therefore, all follow-up care, including the treatment of complications, is included in the global period and cannot be billed separately.

*Because the Instructions for Use states that a hysterosalpingogram is a required part of the Essure procedure, it is considered typical and usual, and will not be paid separately if it is performed within the 90-day global period of the Essure procedure.*

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ESSURE PROCEDURE CODING


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®:

<table>
<thead>
<tr>
<th>Product/Service</th>
<th>CPT Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure procedure</td>
<td>58565</td>
<td>Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Product/Service</th>
<th>HCPCS Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure</td>
<td>A4264</td>
<td>Permanent implantable contraceptive intratubal occlusion device(s) and delivery system</td>
</tr>
</tbody>
</table>

Diagnosis Codes

The International Classification of Diseases, 9th and 10th revisions, Clinical Modification (ICD-9-CM and 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-9-CM and ICD-10-CM codes may be applicable to women who receive Essure:

<table>
<thead>
<tr>
<th>ICD-9-CM Code</th>
<th>ICD-10-CM Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>V25.2</td>
<td>Z30.2</td>
<td>Encounter for sterilization</td>
</tr>
</tbody>
</table>

*CPT codes, descriptions, and other data only are copyright 2015 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association (AMA).
ESSURE CONFIRMATION TEST WITH MODIFIED HYSTEROSALPINGOGRAM (HSG) CODING


The following codes may be used to report procedures associated with Essure®:

<table>
<thead>
<tr>
<th>Product/Service</th>
<th>CPT Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure procedure</td>
<td>58565</td>
<td>Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants</td>
</tr>
<tr>
<td>Modified HSG</td>
<td>58340</td>
<td>Catheterization and introduction of saline or contrast material for saline infusion sonohysterography (SIS) or hysterosalpingography (HSG)</td>
</tr>
<tr>
<td>Modified HSG, interpretation and supervision</td>
<td>74740</td>
<td>HSG, radiologic supervision and interpretation</td>
</tr>
<tr>
<td>Modified HSG, interpretation</td>
<td>74740-26</td>
<td>HSG, radiologic supervision and interpretation, professional component only</td>
</tr>
<tr>
<td>Modified HSG, supervision</td>
<td>74740-TC</td>
<td>HSG, radiologic supervision and interpretation, technical component only</td>
</tr>
</tbody>
</table>

ICD-9-CM and ICD-10-CM diagnosis codes

For many payers, the following codes may be used to identify the Essure Confirmation Test with HSG as a preventive service:

<table>
<thead>
<tr>
<th>ICD-9-CM Code</th>
<th>ICD-10-CM Code</th>
<th>Code Description</th>
<th>Recognized by†:</th>
</tr>
</thead>
<tbody>
<tr>
<td>V25.8</td>
<td>Z30.8</td>
<td>Other specified contraceptive management</td>
<td>Most payers</td>
</tr>
<tr>
<td>V26.51</td>
<td>Z98.51</td>
<td>Tubal ligation status</td>
<td>UHC</td>
</tr>
<tr>
<td>V25.49</td>
<td>Z30.42</td>
<td>Encounter for surveillance of injectable contraceptive</td>
<td>Cigna</td>
</tr>
<tr>
<td>V25.2</td>
<td>Z30.2</td>
<td>Encounter for sterilization</td>
<td>Cigna</td>
</tr>
</tbody>
</table>

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†Subject to change.

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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.

<table>
<thead>
<tr>
<th>Product/Service</th>
<th>CPT Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure procedure</td>
<td>58565-33</td>
<td>Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants</td>
</tr>
<tr>
<td>Modified HSG</td>
<td>58340-33</td>
<td>Catheterization and introduction of saline or contrast material for SIS or HSG</td>
</tr>
</tbody>
</table>

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

Incomplete procedure

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.

<table>
<thead>
<tr>
<th>Product/Service</th>
<th>CPT Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure procedure, reduced services</td>
<td>58565-52</td>
<td>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.</td>
</tr>
<tr>
<td>Essure procedure, discontinued</td>
<td>58565-53</td>
<td>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.</td>
</tr>
</tbody>
</table>

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.

To access state Medicaid coding and reimbursement information, please go to EssureMDResources.com.
AFFORDABLE CARE ACT (ACA) AND COMMERCIAL INSURANCE

Through the Affordable Care Act, Essure® may be available to most patients at no cost

The ACA is reducing financial barriers by requiring most insurance plans to cover women’s birth control and preventive care services without any co-pays, deductibles, or out-of-pocket expenses when their plan renews.¹

Some individual plans may have exemptions, and the availability of the benefits depends on the policy renewal date. When verifying patient benefits, it is important to specifically inquire as to whether the Essure Hysteroscopic Sterilization Procedure (CPT 58565 and/or A4264*) and the Essure Confirmation Test with HSG (58340 and 74740) are covered at NO COST SHARE to the patient as part of the preventive services.

Although most insurers must comply with this new legislation, some plans have limitations or are exempt due to religious affiliation or grandfathered status.¹

How to verify insurance coverage

It is important to verify each patient’s benefits to determine coverage and billing requirements prior to scheduling an Essure placement procedure.

Office personnel may also verify a patient’s Essure coverage by contacting the patient’s health insurance provider directly. The phone number can usually be found on the member’s insurance card.

Be sure to verify coverage and payment levels for both the Essure procedure and Essure Confirmation Test with HSG.

Modifiers

In some cases, adding a modifier to the code may be necessary. Because Essure is considered a preventive service, add a modifier (33) to the procedure code (58565) and Essure Confirmation Test with HSG code (58340).

CPT Modifier 33 is applicable for the identification of preventive services without cost sharing in 4 categories. Essure and the HSG fall under category 4: Preventive care and screenings provided for women (not included in the US Preventive Services Task Force A or B rating) in the comprehensive guidelines supported by the Health Resources and Services Administration.

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

¹If required by Medicaid plan.

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Next step: Schedule the procedure for a date after she becomes eligible.

Because Essure® is considered a preventive service, you may need to add a modifier (33) to the Essure procedure code (58565) and Essure Confirmation Test with HSG code (58340).

Question guide for calling payer

I am calling to verify the sterilization benefits for my patient, _<name>_, under the ACA. Can you please confirm that the Essure procedure and Essure Confirmation Test with HSG (CPT 58565 and/or A4264,* and 58340 and 74740) are available with no cost share for my patient?

This patient is not eligible for preventive services at no cost sharing.

Can you tell me when she will be eligible for preventive services?

Her eligibility begins on her annual renewal date, _<month/year>_.

When her preventive services begin, will 58565 and/or A4264,* and 58340 and 74740 be covered at no cost sharing?

Yes, 58565 and/or A4264,* and 58340 and 74740 are covered at no cost sharing.

Do I need a modifier?

Because Essure® is considered a preventive service, you may need to add a modifier (33) to the Essure procedure code (58565) and Essure Confirmation Test with HSG code (58340).

Can you please verify codes 58565 and/or A4264,* and 58340 and 74740 will be covered under the ACA at that time?

Yes, 58565 and/or A4264,* and 58340 and 74740 are on the list of covered codes.

Can you please confirm the patient will have no financial responsibility when this procedure is performed?

Correct, the claim will be paid at 100%.

NEXT STEP:
Schedule the procedure.
**Employer benefit selection process**

When selecting their benefit plans, employers may choose to only cover certain contraceptive products. Some plans will have limited options available, and Essure® may not necessarily be a covered benefit.

**In order to determine coverage for Essure, it is important to verify each patient’s coverage, as it will vary by payer, plan, region, and employer.**

**MEDICAID**

State Medicaid programs offer comprehensive coverage for contraceptives. However, state Medicaid program eligibility guidelines may vary and could restrict access to Essure for some women. As with private payers, offices should verify coverage prior to treatment. Among women enrolled in Medicaid managed care organizations (MCOs), coverage will be based on MCOs’ policies for Essure. All Medicaid patients have to complete the sterilization consent form a minimum of 30 days prior to the performance of the Hysteroscopic Sterilization procedure.

To access state Medicaid coding and reimbursement information, please go to EssureMDResources.com.

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AFFORDABLE CARE ACT (ACA) QUESTIONS

**Q:** Does the ACA mandate apply to all FDA-approved contraceptives?

**A:** Yes. All FDA-approved contraceptives and sterilization procedures, including Essure®, must be covered with no cost sharing. However, plans may elect to charge cost sharing for branded drugs if a generic version is available. Check with your patient's insurance carrier for specific coverage requirements and cost sharing for that patient.

**Q:** Will the Essure Confirmation Test with HSG also be covered without a cost share component?

**A:** The Essure Confirmation Test with HSG is part of the Essure label and may be covered without a cost share component. As with all contraceptive services and procedures, each patient should confirm benefits and cost share responsibility prior to scheduling the procedure.

**Q:** How does this zero cost sharing affect office reimbursement for products and procedures?

**A:** The contraceptive mandate represents a change in patients' benefits, not reimbursement. Reimbursement for covered products and procedures will vary by payer but should not be directly impacted by the mandate. Healthcare providers should still receive their same contracted rate for products and services, only now the entire amount will be paid by the insurance plan versus collecting a coinsurance, co-pay, or deductible from the patient. Healthcare providers should contact their provider representatives to confirm their reimbursement for Essure procedures.

**Q:** Why are some patients covered by the ACA mandate and others not?

**A:** Some plans have limitations or are exempt from complying with the ACA mandate due to religious beliefs or grandfathered status. Another reason some patients are not covered is because insurers are not required to implement the ACA mandate until their plan renewal date. Some plans renew mid-year in June or July and will update at that time.

**Q:** How does an insurance plan get grandfathered status?

**A:** Plans are grandfathered due to the fact that they have not made major coverage or premium changes since the ACA was passed March 23, 2010. Once a plan makes significant changes, it will lose grandfathered status. Over time, grandfathered plans will lose their status and comply with the legislation.

**Q:** Where can my patients receive assistance when they have a cost share component?

**A:** Refer your patients to the non-profit website called coverher.org, sponsored by the National Women’s Law Center, where she can seek assistance with her required cost share. Additionally, offices can contact their Field Reimbursement Manager through their local Bayer Sales Consultant.
ESSURE®-SPECIFIC QUESTIONS

Q: What is the appropriate CPT code for the healthcare provider to report when performing Hysteroscopic Sterilization?
A: 58565 Hysteroscopic Sterilization with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants.

Q: What is the appropriate ICD-10 diagnosis code for Hysteroscopic Sterilization?
A: Z30.2 Encounter for sterilization.

Q: When is it appropriate to bill for the implants with HCPCS code A4264?
A: Effective January 1, 2010, CMS granted a new HCPCS code to be used by facilities and some Medicaid plans to report Essure: A4264—Permanent implantable contraceptive intratubal occlusion device(s) and delivery system.

CPT 58565 currently includes the cost of the implants in the practice expense, and if not specifically asked by a payer to use A4264 in conjunction with CPT 58565, you risk overbilling for the procedure.

Medicare does not allow for billing with this code. Some individual Medicaid states do allow for use; please call the Essure Reimbursement Line for the specific Medicaid billing requirements in your state.

For private payers, we strongly recommend that you contact each payer with whom you contract to determine if it is appropriate to bill for the implantable devices separately.

Q: How do I know how much I will be reimbursed by payers for Hysteroscopic Sterilization procedures?
A: Your payment will likely be based on your contracted rate with the individual payer. You should contact your provider representative to determine what your actual contracted rate is for Hysteroscopic Sterilization.

Q: What does “facility” versus “non-facility” mean as it relates to healthcare provider payment?
A: In the Medicare Physician Fee Schedule, CPT codes often have two values. The relative value units (RVUs) associated with “facility” denote performance of a service in the inpatient or outpatient hospital and ambulatory surgery center settings. “Non-facility” denotes a procedure performed in an office setting.

The RVUs are usually higher for the non-facility payment, as they include more direct practice expense items and supplies.

Many payers recognize facility and non-facility RVUs. If you are performing an office-based procedure like Hysteroscopic Sterilization, it is important to confirm with your payers that they have set an appropriate fee schedule using non-facility RVUs.

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Q: If I perform Hysteroscopic Sterilization in the office and a mobile provider brings in the hysteroscope tower and all other supplies, how should we each bill?
A: Both entities should bill based on the services provided.
If a provider is performing Essure in the office and has purchased the supplies and the Essure® implants, it is appropriate to bill using the CPT code 58565 (and A4264 if appropriate for the specific payer) and place of service 11.
If the provider is not providing the supplies, Essure implants and/or hysteroscope, there should be a modifier (26, for professional services only) attached to CPT code 58565 signaling reduction of services and supplies. CPT code A4264 would not be billed in this instance.
If a provider is not providing the supplies, Essure implants and/or hysteroscope, there should be a modifier (26, for professional services only) attached to CPT code 58565 indicating the provider is only billing their professional services and not providing supplies or the equipment needed. If the Mobile provider is not providing all of the above, it is appropriate to use a reduced service modifier (52) and submit reduced charges when filing the claim.
If both the physician and the provider bill as if they are the ones purchasing the supplies and implants, this is incorrect and can lead to the payer requesting repayment of overpaid claims. In order to avoid such billing and payment complications, the preferred structure is for the physician to contract with the mobile provider, submit one claim, and then pay the mobile provider an agreed-upon rate.

Q: What is Place of Service (POS)?
A: Place of Service (POS) is the location where the provider provides the medical service. Medicare licenses these entities based on their approved place of service. When submitting claims, all providers must include a place of service code on the claim.
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)

Q: Why are the healthcare provider payments different in the HOPD/ASC than they are in the office?
A: Typically the healthcare provider payments differ in the HOPD/ASC compared with the office because a physician fee schedule is set up to allow for non-facility and facility RVUs.
In the healthcare provider office, the non-facility RVUs for CPT 58565 include the cost of the device and the supplies and medical equipment used during the procedure.
When procedures are performed in the HOPD/ASC, the healthcare provider is not responsible for purchasing the device or supplies necessary to perform the procedure; the ASC carries this responsibility. Therefore, the healthcare provider is paid solely on his/her work RVUs.

Q: What can a healthcare provider charge for procedures performed in the office setting versus the HOPD/ASC?
A: Healthcare providers may create a charge rate for a procedure according to their own calculation of what they believe is reasonable and this becomes the amount that is billed for every procedure performed. It may be a different amount for each site of service, but they must charge all patients the same amounts. Note that this rate is not usually reflective of what the provider will actually be paid by payers with whom they have contracts (the contracted rate).
**Q: What is a contracted rate?**

**A:** The contracted rate is the amount a healthcare provider has contracted to receive for each procedure/service from the payer. Contracted rates vary from healthcare provider to healthcare provider and payer to payer. Contracted rates are usually based on several negotiated factors between the payer and the healthcare provider, including the number of patients they can expect to see for that payer, their geographic relevance to the payer’s network, etc.

**Q: If the RVUs increase, does that mean reimbursement will go up?**

**A:** Not necessarily. In the private-payer world, it will depend on the way the individual healthcare provider contract is structured. For Medicare and Medicaid, rates are set using a formula that includes RVUs plus other factors such as geographic cost of delivering care and average medical malpractice insurance expense (conversion factors). Therefore, an increased RVU will result in an increased payment rate only if the conversion factors set for that year stay the same or increase.

**Q: If our office receives a claim denial, how should we handle this situation?**

**A:** Please contact the Essure Reimbursement Support Line at 1-877-ESSURE2 and press “#.” If the claim is rejected, they will analyze the claim to see if there were any submission errors and provide you with support on how to resubmit if errors are found. If the claim is denied as non-covered or not medically necessary, the Reimbursement Support Line staff can support you in appealing the claim denial.

**Q: How do healthcare providers renegotiate their contracts with payers?**

**A:** Many payers now have “evergreen” contracts, which automatically renew every year after a notice of fee schedule changes is sent to the healthcare provider. If healthcare providers wish to request a change to a specific fee schedule, or if they wish to add a specific CPT code to their allowable codes, they should contact the provider representative for that payer and ask them to outline the process for such a contract change request. It will often involve submission of a formal request letter with supporting materials that justify the request.

**Q: What is the “global period”?**

**A:** The global period is the period of time following each surgery that is included in the global/surgical package established by the payer. Many payers follow CMS (Medicare) guidelines for determining the number of global days. The global period is usually 90 days for major procedures and 0 or 10 days for minor procedures. Therefore, all follow-up care, including the treatment of complications, is included in the global period and cannot be billed separately. Because the Instructions for Use states that a hysterosalpingogram is a required part of the Essure procedure, it is considered typical and usual, and will not be paid separately if it is performed within the 90-day global period of the Essure procedure.

**Q: Should the office staff provide an invoice when submitting a claim?**

**A:** It is not necessary to send an invoice unless the payer specifically asks for it.

**Q: Do all patients have to complete a sterilization consent form 30 days prior to their Hysteroscopic Sterilization procedure?**

**A:** All Medicaid patients have to complete the sterilization consent form a minimum of 30 days prior to the performance of the Hysteroscopic Sterilization procedure.

**Q: What additional support is available to assist me with the Essure process?**

**A:** Bayer offers reimbursement assistance through our dedicated Field Reimbursement Management team. These individuals function in a non-sales role to offer reimbursement support and expertise as needed. Your sales consultant can provide more details about this resource, or you can visit EssureMD.com.

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