Sterilization

This section includes instructions to bill for sterilization services.

**Human Reproductive Sterilization Defined**

Under the regulations, human reproductive sterilization is defined as any medical treatment, procedure or operation for the purpose of rendering an individual permanently incapable of reproducing. Sterilizations which are performed because pregnancy would be life threatening to the mother (so-called “therapeutic” sterilizations) are included in this definition. The term sterilization, as used in Medi-Cal regulations, means only human reproductive sterilization, as defined above.

**Note:** For hysterectomy policy, refer to the *Hysterectomy* section in this manual.

**Coverage Conditions**

The conditions under which sterilization procedures for both inpatient and outpatient services are reimbursable by the Medi-Cal program conform to federal regulations.

A sterilization will be covered by Medi-Cal only if the following conditions are met:

1. The individual is at least 21 years old at the time written consent for sterilization is obtained.

   **Note:** Under Medi-Cal regulations, a patient must be 21 years old to give consent to a sterilization. This is a federal requirement for sterilizations only and is not affected by state law regarding the ability to give consent to medical treatment generally. The age limit is an absolute requirement. There are no exceptions for marital status, number of children or for a therapeutic sterilization.

2. The individual is not mentally incompetent. A mentally incompetent individual is a person who has been declared mentally incompetent by the federal, state or local court of competent jurisdiction for any purposes which include the ability to consent to sterilization.

3. The individual is able to understand the content and nature of the informed consent process as specified in this section. A patient considered mentally ill or with intellectual disabilities may sign the consent form if it is determined by a physician that the individual is capable of understanding the nature and significance of the sterilizing procedure.
4. The individual is not institutionalized. For the purposes of Medi-Cal reimbursement for sterilization, an institutionalized individual is a person who is:
   - Involuntarily confined or detained under civil or criminal statute in a correctional or rehabilitative facility, including a mental hospital or other facility for the care and treatment of mental illness; or
   - Confined under a voluntary commitment in a mental hospital or other facility for the care and treatment of mental illness.

5. The individual has voluntarily given informed consent in accordance with all the requirements prescribed in this section.

6. At least 30 days, but not more than 180 days, have passed between the date of the written and signed informed consent and the date of the sterilization, except in the following instances:
   - Sterilization may be performed at the time of emergency abdominal surgery if:
     - The patient consented to the sterilization at least 30 days before the intended date of sterilization, and
     - At least 72 hours have passed after written informed consent was given and the performance of the emergency surgery.
   - Sterilization may be performed at the time of premature delivery if the following requirements are met:
     - The written informed consent was given at least 30 days before the expected date of the delivery, and
     - At least 72 hours have passed after written informed consent to be sterilized was given.

7. A completed consent form must accompany all claims for sterilization services. This requirement extends to all providers, attending physicians or surgeons, assistant surgeons, anesthesiologists and facilities. However, only claims directly related to the sterilization surgery require consent documentation. Claims for presurgical visits and tests or services related to postsurgical complications do not require consent documentation.
Informed Consent Process

The informed consent process may be conducted either by a physician or by the physician’s designee.

An individual has given informed consent only if:

1. The person who obtained consent for the sterilization procedure:
   - Offered to answer any questions the individual may have had concerning the sterilization procedure, and
   - Provided the individual with a copy of the consent form and the booklet on sterilization published by the Department of Health Services, and
   - Provided orally all of the following information to the individual to be sterilized:
     - Advice that the individual is free to withhold or withdraw consent to the procedure at any time before the sterilization without affecting the right to future care or treatment and without loss or withdrawal of any federally funded program benefits to which the individual might be otherwise entitled.
     - A full description of available alternative methods of family planning and birth control.
     - Advice that the sterilization procedure is considered to be irreversible.
     - A thorough explanation of the specific sterilization procedure to be performed.
     - A full description of the discomforts and risks that may accompany or follow performing the procedure, including an explanation of the type and possible effects of any anesthetic to be used.
     - A full description of the benefits or advantages that may be expected as a result of the sterilization.
     - Approximate length of hospital stay.
     - Approximate length of time for recovery.
     - Financial cost to the patient.
     - Information that the procedure is established or new.
     - Advice that the sterilization will not be performed for at least 30 days, except under the circumstances of premature delivery or emergency abdominal surgery.
     - The name of the physician performing the procedure; if another physician is to be substituted, the patient shall be notified of the physician’s name and the reason for the change in physicians prior to administering preanesthetic medication.
2. Suitable arrangements were made to ensure that the information specified above was effectively communicated to any individual who is blind, deaf, or otherwise handicapped.

3. An interpreter was provided if the individual to be sterilized did not understand the language used on the consent form or the language used by the person obtaining consent.

4. The individual to be sterilized was permitted to have a witness of the individual’s choice present when consent was obtained.

5. The sterilization operation was requested without fraud, duress, or undue influence.

6. The appropriate consent form was properly filled out and signed.

7. Informed consent may not be obtained while the individual to be sterilized is:
   - Under the influence of alcohol or other substances that affect the individual’s state of awareness.
   - In labor or within 24 hours postpartum or postabortion.
   - Seeking to obtain or obtaining an abortion.
     - “Seeking to obtain” means that period of time during which the abortion decision and the arrangements for the abortion are being made.
     - “Obtaining an abortion” means that period of time during which an individual is undergoing the abortion procedure, including any period during which preoperative medication is administered.

Medi-Cal regulations prohibit the giving of consent to a sterilization at the same time a patient is seeking to obtain or obtaining an abortion. This does not mean, however, that the two procedures may never be performed at the same time. If a patient gives consent to sterilization, then later wishes to obtain an abortion, the procedures may be done concurrently. An elective abortion does not qualify as emergency abdominal surgery, and this procedure does not affect the 30-day minimum wait.
Sterilization Consent Form (PM 330): General Information

The only sterilization consent form accepted by Medi-Cal is the Department of Health Services’ Consent Form (PM 330). Claims submitted with a computer generated form or any other preprinted version of the PM 330 will not be reimbursed. However, specific information may be pre-stamped or typed as identified in “Sterilization Consent Form Instructions” in this section. The form may then be photocopied prior to being completed and signed. Photocopies will be accepted only if the entire form is legible.

A sample PM 330 and instructions for completing the form are included in this section. The numbered items correspond to the numbers on Figures 1 and 2 on the following pages. These instructions must be followed exactly or the Consent Form will be returned and reimbursement delayed. The sterilization Consent Form requirements are imposed by the Federal government and can be found in California Code of Regulations, Title 22, Section 51305.4.

Ordering Forms

Sterilization Consent Forms (in English and Spanish) can be downloaded from the Forms page of the Medi-Cal website located at www.medi-cal.ca.gov or ordered by calling the Telephone Service Center (TSC) at 1-800-541-5555. Providers must supply their NPI number when ordering the form(s). The following information also may be requested:

- Date
- Name of document (sterilization Consent Form, PM 330)
- Name of provider/facility (registered provider name associated with the NPI)
- Complete shipping address: Street, city, state, ZIP code (P.O. Box not accepted)
- Quantity of forms requested
- Contact person and telephone number
Sterilization Consent Form Instructions

1. **Name of physician or clinic.** Name of the doctor, group, clinic or hospital. If the provider is a physician group, all names may appear (for example, Drs. Miller and Smith), the professional group name may be listed (for example, “Westside Medical Group”) or the phrase “and/or his/her associates” may be used. His line may be pre-stamped or typed.

2. **Name of procedure.** Enter the full name of the procedure. If completing the Consent Form in Spanish, the name of the procedure may be written in Spanish. Must be consistent throughout the Consent Form (numbers 2, 6, 13 and 20) and must match name of procedure on the claim. This line may be pre-stamped or typed.

3. **Patient’s birthdate.** Month, day and year required and must match the patient’s date of birth on the claim. The patient must be at least 21 years of age at the time consent is obtained.

4. **Patient’s name.** Must be consistent throughout the Consent Form (numbers 4, 7, 12 and 18) and must match the patient’s name on the claim. Print the last name first; use one letter per square.

5. **Physician’s name.** If a group, all provider’s names may be listed, or the phrase “and/or his/her associates.” This line may be pre-stamped or typed.

6. **Name of procedure.** Enter the full name of the procedure. If completing the Consent Form in Spanish, the name of the procedure may be written in Spanish. Must be consistent throughout the Consent Form (numbers 2, 6, 13 and 20). This line may be pre-stamped or typed.

7. **Patient’s signature.** If the patient signs the consent form with an “X”, a symbol/character or in a non-Arabic alphabet, the signature must be countersigned by a witness. Must be consistent throughout the Consent Form (numbers 4, 7, 12 and 18).

8. **Date.** Patient’s signature must be dated with month/day/year. The required 30-day waiting period is calculated from this date.

Interpreter’s Statement

9. **Language.** Indicate the language in which the patient was counseled, if other than English or Spanish.

10. **Interpreter’s signature.** A signature is required if an interpreter was used.

11. **Date.** Interpreter’s signature must be dated with month/day/year.
Statement Of Person Obtaining Consent

12. **Patient’s name.** Patient’s name must be consistent throughout the *Consent Form* (numbers 4, 7, 12 and 18) and must match the patient’s name on the claim.

13. **Name of procedure.** Enter the full name of the procedure. If completing the *Consent Form* in Spanish, the name of the procedure may be written in Spanish. Must be consistent throughout the *Consent Form* (numbers 2, 6, 13 and 20). This line may be pre-stamped or typed.

14. **Signature of person obtaining consent.** Signature required from person providing sterilization counseling; it may be a physician or the physician’s designee.

15. **Date.** Signature of the person obtaining consent must be dated with month/day/year.

16. **Name of facility.** Name of place where patient was given sterilization counseling, for example, a physician’s office, clinic, etc. (Not necessarily the facility where the procedure was performed.) May be pre-stamped or typed.

17. **Address of facility.** Complete mailing address of facility identified in number 16. Must include street address, city, state and ZIP code. Once this section is completed, the patient must be given a copy of the consent form. May be pre-stamped or typed.

Physician’s Statement

18. **Patient’s name.** Patient’s name must be consistent throughout the *Consent Form* (numbers 4, 7, 12 and 18) and must match the patient’s name on the claim.

19. **Date.** Enter month/day/year. This date must match the date of the procedure on the claim.

20. **Name of procedure.** Enter the full name of the procedure. If completing the *Consent Form* in Spanish, the name of the procedure may be written in Spanish. Must be consistent throughout the *Consent Form* (numbers 2, 6, 13 and 20). This line may be pre-stamped or typed.

21. **Paragraph one.** Do not cross off paragraph one if the minimum waiting period of 30 days has been met; cross off paragraph two if the minimum waiting period of 30 days has been met.

22. **Paragraph two.** Do not cross off paragraph two if the minimum waiting period of 30 days has not been met; cross off paragraph one if the minimum waiting period of 30 days has not been met. In addition, mark either box “A” for premature delivery or box “B” for emergency abdominal surgery.
23. **Premature delivery.** Mark box “A” if the minimum waiting period of 30 days has **not** been met due to a premature delivery. Complete date of premature delivery (number 24) and date delivery was **expected** (number 25).

24. **Premature delivery date.** Date of premature delivery with month/day/year. This date must be at least 72 hours from the date consent was given by the patient and the date of the sterilization procedure. Must be completed if box “A” is marked.

25. **Individual’s expected date of delivery.** Date of patient’s **expected** delivery with month/day/year as estimated by physician based on the patient’s history and physical condition. Must be completed if box “A” is marked. This date must be at least 30 days from the date consent was given by the patient (as identified in number 8).

26. **Emergency abdominal surgery.** Mark box “B” if the minimum waiting period of 30 days **was not** met due to emergency abdominal surgery or if 72 hours has not passed between the date the patient gave consent and the date of the emergency abdominal surgery. Enter name of the operation performed and describe the circumstances.

27. **Physician’s signature.** Signature of the physician who has verified consent and who actually performed the operation is required.

28. **Date.** Physician’s signature must be dated with month/day/year. Date must be on or after the sterilization date (refer to number 19).
Figure 1: Sample Sterilization Consent Form (PM 330) – English Side.

Part 2 – Sterilization
**CONSENT FORM - PM 330**

**NOTA:** NINGUNO DE LOS BENEFICIOS QUE RECIBO DE LOS PROGRAMAS O PROYECTOS SUBSIDIADOS CON FONDS FEDERALES SE ME CANCELARÁ O SUSPENDERÁ EN CASO DE QUE YO DECIDA NO ESTERILIZARME.

### CONSENTIMIENTO PARA ESTERILIZACIÓN

Declaro que, he solicitado y obtenido información sobre esterilización de:

1. **Al solicitar información se me dijo que yo soy la única persona que puede decidir esterilizarme o no y que estoy en**
   mi derecho a negarme a ser esterilizada. Mi decisión de no esterilizarme no**
   afectará mi derecho a recibir atención o tratamiento médico en el futuro, y**
   tampoco dejaré de recibir ningún tipo de asistencia o beneficios que recibo**
   actualmente de los programas subsidiados con fondos federales, tales como**
   A.F.D.C. o Medicare o de aquellos a los que pudiera tener derecho en el futuro.

**ENTENDIDO QUE LA ESTERILIZACIÓN DEBER SE CONSIDERADA**

PERMANENTE E INVEROSIMIL. DECLARO QUE ES MI DECISIÓN EL NO

**QUERER VOLVER A EMBARAZARSE, DAR A LUZ O SER PADRE**

NUEVAMENTE.

Declaro que se me ha informado acerca de la existencia de otros métodos anticonceptivos temporales que están a mi disposición y que me permitirían en un futuro tener hijos o ser padre nuevamente. Sin embargo, he renunciado a estos métodos alternativos y he decidido esterilizarme.

**ENTENDIDO QUE SE ME VA A ESTERILIZAR MEDIANTE UN MÉTODO CONOCIDO COMO:**

2. **(Nombre del procedimiento)**

Declaro que me explicaron los malestares, riesgos y beneficios asociados con la operación, y que se respondió a todas mis preguntas satisfactoriamente.

**ENTENDIDO QUE LA OPERACIÓN SE LLEVARÁ A CABO HASTA POR LO MÉNOS**

(Tiempo) días después de que firme este formulario, y que puedo cambiar de parecer en cualquier momento y decidir no esterilizarme. Si decidio no esterilizarme, no**

dejaré de recibir ninguno de los beneficios o servicios médicos ofrecidos por los**

programas subsidiados con fondos federales.

Declaro que tengo al menos 21 años de edad y que naci en**

3. **(Lugar)**

**CONSIDERACIÓN DE LA PERSONA QUE RECIBE EL CONSENTIMIENTO**

Declaro que antes de que,**

12. **(Nombre de la persona a ser esterilizada)**

firmara el formulario de consentimiento, le explicaré la naturaleza del método**

esterilización conocido como**

13. **(Nombre del procedimiento)**

**ENTENDIDO QUE EL MEDICO SE arsen a explicarme la naturaleza del procedimiento**

y la posibilidad de tomar medidas alternativas. También le explicaré la obligación de**

apuntar una fecha para la esterilización en el formulario de consentimiento.

**DECLARACIÓN DEL MÉDICO**

Declaro que lo que se ha explicado al paciente es coherente con las leyes y normativas en vigor. Conozco la importancia de explicar adecuadamente el procedimiento a ser realizado, y además, que la elección final de proceder o no a la esterilización

**ENTENDIDO QUE LA ESTERILIZACIÓN ES PERMANENTE**

y no puede ser revertida en un futuro.

4. **(Nombre del procedimiento)**

**ENTENDIDO QUE EL MÉTODO ES EFEKTIVO**

y no puede ser revertido en un futuro.

5. **(Nombre del procedimiento)**

**DECLARACIÓN DEL PATIENTE**

Declaro que, he firmado el consentimiento y se ha sellado con un sello o firma.

6. **(Firma del paciente)**

**DECLARACIÓN DEL ÍNTRÉPRETE**

Si se requiere de un intérprete para asistir a la persona que va a ser esterilizada:

7. **(Nombre del intérprete)**

Declaro que he traducido la información y los consejos verbales que la persona que**

rechazó el consentimiento se ha dado a la persona que va a ser esterilizada. También**

le he explicado su contenido. A mi mejor saber y entender dicha persona ha comprendido las**

explicaciones que le dieron.

8. **(Fecha)**

**DECLARACIÓN DEL MÉDICO**

Declaro que lo que se ha explicado al paciente es coherente con las leyes y normativas en vigor. Conozco la importancia de explicar adecuadamente el procedimiento a ser realizado, y además, que la elección final de proceder o no a la esterilización

9. **(Nombre del médico)**

**DECLARACIÓN DEL PATIENTE**

Declaro que, he firmado el consentimiento y se ha sellado con un sello o firma.

10. **(Firma del paciente)**

**DECLARACIÓN DEL ÍNTRÉPRETE**

Si se requiere de un intérprete para asistir a la persona que va a ser esterilizada:

11. **(Nombre del intérprete)**

Declaro que he traducido la información y los consejos verbales que la persona que**

rechazó el consentimiento se ha dado a la persona que va a ser esterilizada. También**

le he explicado su contenido. A mi mejor saber y entender dicha persona ha comprendido las**

explicaciones que le dieron.

12. **(Fecha)**

**DECLARACIÓN DEL MÉDICO**

Declaro que lo que se ha explicado al paciente es coherente con las leyes y normativas en vigor. Conozco la importancia de explicar adecuadamente el procedimiento a ser realizado, y además, que la elección final de proceder o no a la esterilización

13. **(Nombre del médico)**

**DECLARACIÓN DEL PATIENTE**

Declaro que, he firmado el consentimiento y se ha sellado con un sello o firma.

14. **(Firma del paciente)**

**DECLARACIÓN DEL ÍNTRÉPRETE**

Si se requiere de un intérprete para asistir a la persona que va a ser esterilizada:

15. **(Nombre del intérprete)**

Declaro que he traducido la información y los consejos verbales que la persona que**

rechazó el consentimiento se ha dado a la persona que va a ser esterilizada. También**

le he explicado su contenido. A mi mejor saber y entender dicha persona ha comprendido las**

explicaciones que le dieron.

16. **(Fecha)**

### DECLARACIÓN DEL MédICO

Declaro que lo que se ha explicado al paciente es coherente con las leyes y normativas en vigor. Conozco la importancia de explicar adecuadamente el procedimiento a ser realizado, y además, que la elección final de proceder o no a la esterilización

17. **(Nombre del médico)**

**DECLARACIÓN DEL PATIENTE**

Declaro que, he firmado el consentimiento y se ha sellado con un sello o firma.

18. **(Firma del paciente)**

**DECLARACIÓN DEL ÍNTRÉPRETE**

Si se requiere de un intérprete para asistir a la persona que va a ser esterilizada:

19. **(Nombre del intérprete)**

Declaro que he traducido la información y los consejos verbales que la persona que**

rechazó el consentimiento se ha dado a la persona que va a ser esterilizada. También**

le he explicado su contenido. A mi mejor saber y entender dicha persona ha comprendido las**

explicaciones que le dieron.

20. **(Fecha)**

**DECLARACIÓN DEL MÉDICO**

Declaro que lo que se ha explicado al paciente es coherente con las leyes y normativas en vigor. Conozco la importancia de explicar adecuadamente el procedimiento a ser realizado, y además, que la elección final de proceder o no a la esterilización

21. **(Nombre del médico)**

**DECLARACIÓN DEL PATIENTE**

Declaro que, he firmado el consentimiento y se ha sellado con un sello o firma.

22. **(Firma del paciente)**

**DECLARACIÓN DEL ÍNTRÉPRETE**

Si se requiere de un intérprete para asistir a la persona que va a ser esterilizada:

23. **(Nombre del intérprete)**

Declaro que he traducido la información y los consejos verbales que la persona que**

rechazó el consentimiento se ha dado a la persona que va a ser esterilizada. También**

le he explicado su contenido. A mi mejor saber y entender dicha persona ha comprendido las**

explicaciones que le dieron.

24. **(Fecha)**

**DECLARACIÓN DEL MÉDICO**

Declaro que lo que se ha explicado al paciente es coherente con las leyes y normativas en vigor. Conozco la importancia de explicar adecuadamente el procedimiento a ser realizado, y además, que la elección final de proceder o no a la esterilización

25. **(Nombre del médico)**

**DECLARACIÓN DEL PATIENTE**

Declaro que, he firmado el consentimiento y se ha sellado con un sello o firma.

26. **(Firma del paciente)**

**DECLARACIÓN DEL ÍNTRÉPRETE**

Si se requiere de un intérprete para asistir a la persona que va a ser esterilizada:

27. **(Nombre del intérprete)**

Declaro que he traducido la información y los consejos verbales que la persona que**

rechazó el consentimiento se ha dado a la persona que va a ser esterilizada. También**

le he explicado su contenido. A mi mejor saber y entender dicha persona ha comprendido las**

explicaciones que le dieron.

28. **(Fecha)**

PM 330 (1/99) (Sp)

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**Figure 2:** Sample Sterilization Consent Form (PM 330) – Spanish Side

Part 2 – Sterilization
Dear Medi-Cal Provider,

California Medicaid Management Information System (California MMIS) Fiscal Intermediary has received your claim for sterilization services performed under the Medi-Cal program. In reviewing the sterilization Consent Form accompanying your claim, we identified area(s) of insufficient or incorrect information. As this information is required by state and federal rules and regulations for sterilizations performed under the Medi-Cal program, we are unable to process your claim as it was submitted.

To facilitate the resolution of your denied claim, we have enclosed the materials necessary for properly completing the sterilization Consent Form in accordance with Medi-Cal specifications. These materials include the following:

- A copy of your original claim.
- A sample sterilization Consent Form, indicating the specific information required by the California MMIS Fiscal Intermediary for proper claim adjudication.

The sample sterilization Consent Form included with this letter shows the fields of information labeled numerically. To the right of the sample form is a corresponding explanation for each of these fields (numbers). We have marked on this sample form the fields (numbers) for which you must provide either corrected or additional information so that we can process your claim. These fields are marked with an "X."

Please provide the correct and/or additional information, designated with an "X" on the sample sterilization Consent Form, in the corresponding field on the copy of your original sterilization Consent Form. For example, is number 4, "Patient's Name," is designated with an "X" on the sample sterilization Consent Form, provide the appropriate information in the corresponding field on the copy of your original sterilization Consent Form.

Please return the following to the California MMIS Fiscal Intermediary, P.O. Box 13039, Sacramento, CA 95813-4929:

- The copy of your original claim.
- The corrected copy of your original sterilization Consent Form.
- A copy of the Remittance Advice Details (RAD) showing the denied claim.
- A completed Claims Inquiry Form (CIF). (The CIF cannot be completed and sent to the California MMIS Fiscal Intermediary until the claim has actually appeared as denied on a RAD)

NOTE
For more information, see the Sterilization section in your Inpatient/Outpatient or Medical Services Provider Manual.

For instructions about submitting the CIF and timeliness guidelines, refer to the CIF sections in your provider manual. If you need further assistance in filing claims for sterilization services rendered under the Medi-Cal program, refer to your provider manual or contact the Telephone Service Center (TSC) at 1-800-541-5655.

Figure 3. Sterilization Consent Form (88-H-20) Correction Letter.

Part 2 – Sterilization
Sample Sterilization Consent Form for Medi-Cal Billing

CCN: ____________________

STATEMENT OF PERSON OBTAINING CONSENT

[Form information]

PHYSICIAN’S STATEMENT

[Form information]

INTERPRETER’S STATEMENT

[Form information]

For more information, refer to your Medi-Cal provider manual or call 1-800-541-5555.

88-4-20 (9/18)

Figure 4: Sample Sterilization Consent Correction Form.

Part 2 – Sterilization
**Sterilization Consent Form Signature**

1. The *Consent Form* must be signed and dated by the:
   - individual to be sterilized,
   - interpreter, if one is provided,
   - individual who obtains the consent, and
   - physician who performed the sterilization procedure.

2. The person securing consent shall certify by signing the *Consent Form* that he or she:
   - advised the individual to be sterilized, before the individual to be sterilized signed the *Consent Form*, that no federal benefits may be withdrawn because of the decision not to be sterilized.
   - explained orally the requirements for informed consent to the individual to be sterilized as set forth on the *Consent Form* and in regulations.
   - determined to the best of his/her knowledge and belief that the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

3. The physician performing the sterilization shall certify by signing the *Consent Form* that:
   - the physician, shortly before the performance of the sterilization, advised the individual to be sterilized that federal benefits shall not be withheld or withdrawn because of a decision not to be sterilized. (For the purposes of Medi-Cal regulations, the phrase “shortly before” means a period within 72 hours prior to the time the patient receives any preoperative medication.)
   - the physician explained orally the requirements for informed consent as set forth on the *Consent Form*.
   - to the best of the physician’s knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.
• at least 30 days have passed between the date of the individual’s signature on the Consent Form and the date the sterilization was performed, except in the following instances:

  – Sterilization may be performed at the time of emergency abdominal surgery if the physician certifies that the patient consented to the sterilization at least 30 days before he/she intended to be sterilized; that at least 72 hours have passed after written informed consent to be sterilized was given; and the physician describes the emergency on the Consent Form.

  – Sterilization may be performed at the time of premature delivery if the physician certifies that the written informed consent was given at least 30 days before the expected date of the delivery. The physician shall state the expected date of the delivery on the Consent Form. At least 72 hours have passed after written informed consent to be sterilized was given.

4. The interpreter, if one is provided, shall certify that he or she

  • transmitted the information and advice presented orally to the individual to be sterilized

  • read the Consent Form and explained its contents to the individual to be sterilized, and

  • determined to the best of his/her knowledge and belief that the individual to be sterilized understood what the interpreter told the individual.

5. A copy of the signed Consent Form must be:

  • provided to the patient

  • retained by the physician and the hospital in the patient’s medical records, and

  • attached to all claims for sterilization services. This requirement extends to all providers: attending physicians or surgeons, assistant surgeons, anesthesiologists and facilities. Only claims directly related to the sterilization surgery, however, require consent documentation. Claims for presurgical visits and tests or services related to postsurgical complications do not require consent documentation.

Before obtaining consent, the person who obtains consent must provide the individual to be sterilized with a copy of the informational brochure on sterilization, which can be downloaded and printed in both English and Spanish from the Permanent Birth Control page of the Department of Health Care Services (DHCS) website located at http://www.dhcs.ca.gov/Pages/PermanentBirthControl.aspx. Instructions regarding how to print these brochures can be found at: http://www.dhcs.ca.gov/Pages/PrintingInstructions.aspx.
Sterilization Consent Form Corrections

Providers whose claims are denied as a result of incorrectly completed sterilization Consent Forms will receive a package from the California MMIS Fiscal Intermediary, with the materials required for correcting the sterilization Consent Form. The package will include a letter explaining the process of correcting the sterilization Consent Form (see Figure 3), a sample sterilization Consent Form (see Figure 4) indicating the fields (numbers) on the form that were either completed incorrectly or contained insufficient information and a copy of the original claim.

The sample sterilization Consent Form (Figure 4), found on the reverse side of the letter, shows all of the fields on the form labeled numerically. An explanation of each field is presented to the right of the sample sterilization Consent Form. The field(s) marked with an “X” on the sample sterilization Consent Form is the field(s) that was either not completed or completed incorrectly on the original sterilization Consent Form.

The provider must make the appropriate correction(s) on his or her copy of the original sterilization Consent Form. For example, if the information for number 3, “Patient’s Birthdate,” is marked with an “X” on the sample sterilization Consent Form, the provider should enter the appropriate information in number 3 on their copy of the original sterilization Consent Form. All changed information should be initialed. Do not use correction fluid to blot out errors. Errors should be lined out.

The corrected copy of the original sterilization Consent Form, the copy of the original claim, a copy of the Remittance Advice Details (RAD) showing the denied claim, and a completed Claims Inquiry Form (CIF) should be returned to:

California MMIS Fiscal Intermediary  
P.O. Box 15300  
Sacramento, CA 95851-1300

The package received by the provider is an indication that the sterilization claim either has or will soon appear on a RAD as a denied claim. The CIF cannot be completed and sent to the California MMIS Fiscal Intermediary until the claim has actually appeared as denied on a RAD. All guidelines requiring timeliness and completion of the CIF should be followed.
Tubal Ligations

A tubal ligation performed during the same hospitalization as a vaginal delivery (CPT® code 58605), or at the time of a cesarean section or intra-abdominal surgery (CPT code 58611), is covered by Medi-Cal as a separately reimbursable service. If the tubal ligation is performed at the time of a cesarean section or intra-abdominal surgery, providers must follow these guidelines.

Physicians must use:

- Modifier AG (primary physician) to bill for the C-section or intra-abdominal surgery
- Modifier 51 to bill for the tubal ligation (CPT code 58611)
- A sterilization Consent Form (PM 330)

Note: Assistant Surgeons must bill code 58611 with modifier 99. The Additional Claim Information field (Box 19) of the CMS-1500 claim must note that modifier 99 was used to signify “modifier 80 and modifier 51.”

Removal of Fallopian Tubes

If a laparoscopy with removal of the adnexal structures (CPT code 58661), salpingectomy (CPT code 58700) or a salpingo-oophorectomy (CPT code 58720) is performed, the claim must clearly indicate whether the procedure was:

- A unilateral procedure that will not produce sterility
- A bilateral procedure that will produce sterility

When one of the above procedures will result in sterilization, a sterilization Consent Form (PM 330) and an approved Treatment Authorization Request (TAR) are required. If CPT codes 58661 and 58700 are elective sterilization procedures, there is no TAR requirement. Consent Form (PM 330) remains a requirement in elective sterilization procedures. Refer to “Sterilization Consent Form Required” in this section for guidelines.

Subtotal or Total Hysterectomy After Cesarean Delivery

Reimbursement for CPT code 59525 (subtotal or total hysterectomy after cesarean delivery) does not require informed consent but does require that a handwritten statement, signed by the physician certifying the nature of the emergency, accompany the claim. The certification of emergency must appear in the Remarks field (Box 80)/Additional Claim Information field (Box 19) of the claim form or on an attachment.

Refer to the Hysterectomy section in this manual for additional information.
Authorization for Interval Inpatient Sterilizations

Authorization is required for most inpatient sterilizations, except those performed on a postpartum basis, such as a tubal ligation. Since sterilizations normally can be performed as an outpatient procedure, the TAR should clearly indicate why hospitalization is required. TARs for the inpatient hospitalization need not include consent documentation, but the completed PM 330 must accompany the claim for the procedure.

Hysterosalpingogram

A hysterosalpingogram (CPT code 74740) is not reimbursable if performed within three months following a tubal occlusion/transection/ligation procedure. See “Policy Conditions” under Essure for billing code 74740 as follow-up to placement of Essure.

Essure System ESS305

Hysteroscopy surgical, with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants (CPT code 58565) is a Medi-Cal benefit. The Essure System ESS305 micro-insert procedure is considered experimental and investigational for all other indications and may be reimbursed when billed with CPT code 58565 for the procedure and HCPCS code A4264 (permanent implantable contraceptive intratubal occlusion device[s] and delivery system) only. Placement of the Essure micro-inserts does not require general anesthesia and is designed to be performed in a physician’s office. However, as clinically indicated it may be performed in an ambulatory surgery center or hospital outpatient surgery center.

Policy Conditions

The policy conditions below must be followed to ensure correct reimbursement:

- The Essure System ESS305 must be ordered from Bayer Corporation as the sole-source provider and be purchased only by physicians who have completed the company-sponsored training course and who have earned the training certification. For each provider who inserts the Essure System ESS305, the certificate of training must be retained by the provider and is subject to post-payment review.

- Hospital outpatient departments and outpatient clinics may purchase the Essure System ESS305 from Bayer Corporation, but must have verification that the physician who will perform the procedure has completed the company-sponsored training course and has earned the training certificate. The certificate of training for each provider who inserts the Essure System ESS305 must be retained by the outpatient department or clinic is subject to post-payment audit.
- Providers must maintain a written log or electronic record of all Essure micro-inserts placed, including the recipient’s name, medical record, or Medi-Cal Benefits Identification Card (BIC) number, date of surgery, and lot number of the product, for at least five years from the date of insertion. This is subject to post payment audit.

- CPT code 58565 and HCPCS code A4264 are subject to all federal and state sterilization policy. Recipients must be 21 years of age or older. A Consent Form (PM 330) is always required, even when the procedure is not successful.

- Before attempting placement of the Essure micro-inserts, the physician must perform a thorough hysteroscopic evaluation of the uterine cavity. Tubal or uterine anomalies may make it impossible to place the Essure micro-insert. No attempt should be made to place a micro-insert in one tubal ostium unless there is a reasonable expectation that the opposite tubal ostium is accessible and patent. It is mandatory that the Essure micro-insert system remains within the sterile packaging until both tubal ostia are visualized. If there is a doubt about successful bilateral placement, then the procedure should be terminated and the provider bill with CPT code 58555 (hysteroscopy, diagnostic).

- If a provider is not successful in performing a bilateral placement of the Essure micro-inserts, a second attempt to occlude the open fallopian tube may be reimbursed. The same provider will not be reimbursed if more than two attempts are required to successfully achieve bilateral placement. A different provider may be reimbursed for only one additional attempt to perform the unilateral placement of the micro-insert to achieve the bilateral occlusion.

- Bilateral placement of an Essure System ESS305 is restricted to once-in-a-lifetime per recipient, any provider.

- Unilateral placement of an Essure System ESS305 is restricted to twice-in-a-lifetime per recipient, any provider.

- A hysterosalpingogram (CPT code 74740) must be performed at 12 weeks after placement of Essure to confirm bilateral tubal occlusion. If tubal occlusion cannot be confirmed at that time, the hysterosalpingogram must be repeated 12 weeks from the date of the first hysterosalpingogram.

- Providers must bill CPT code 74740 in conjunction with diagnosis code Z98.51 (tubal ligation status) when billed as a follow-up to placement of Essure.
Reimbursement
The reimbursement for code 58565 includes the procedure and supplies. The device is reimbursed with HCPCS code A4264. No invoice is required.

Diagnosis Code
Codes 58565 and A4264 will only be reimbursed when billed in conjunction with ICD-10-CM diagnosis code Z30.2 (encounter for sterilization).

Modifiers
CPT code 58565 must be billed with one of the following modifiers: 50, 52, 99, UA or UB. The procedure is billed with modifier 50 or 52 and the supplies are billed with modifier UA or UB. Each modifier must be billed on a separate claim line.

HCPCS code A4264 must be billed with modifier 50 if inserted bilaterally, or modifier 52 if inserted unilaterally.

- When code A4264 is billed with modifier 50 (bilateral placement of Essure micro-inserts), reimbursement is restricted to once-in-a-lifetime, same recipient, any provider.
- When code A4264 is billed with modifier 52 (unilateral placement of Essure micro-inserts), reimbursement is restricted to twice-in-a-lifetime, same recipient, any provider.

Modifier AG Disallowed With Code 58565
CPT code 58565 must not be billed with modifier AG. This is an exception to the Medi-Cal billing policy that requires modifier AG (primary surgeon) to be billed with surgical CPT codes.

Assistant Surgeon Services Not Reimbursable
Neither CPT code 58565 nor A4264 are reimbursable for assistant surgeons.

Code 58555
Failed attempts of either a bilateral or unilateral placement of Essure micro-inserts should be billed with CPT code 58555 (hysteroscopy, diagnostic).

Supplies: Modifier UA or UB
When code 58565 is billed with modifier UA or UB (supplies) reimbursement is restricted to three times in a lifetime, same recipient, any provider.
CMS-1500 Example: Bilateral Procedure

The following is an example of a bilateral placement of the Essure micro-inserts. Each modifier is billed on a separate line.

Because this claim is submitted with a diagnosis code, an ICD indicator is required between the dotted lines in the *ICD Ind.* area of Box 21. An indicator is required only when an ICD-10-CM/PCS code is entered on the claim.
UB-04 Example: Bilateral Procedure

The following is an example of a bilateral placement of the Essure micro-inserts. Each modifier is billed on a separate line. A Consent Form (PM 330) must accompany claims for sterilization services. Refer to the UB-04 Completion: Outpatient Services section in this manual for the appropriate type of bill needed for the facility billing the service.

Because this claim is submitted with a diagnosis code, an ICD indicator is required in the white space below the DX field (Box 66). An indicator is required only when an ICD-10-CM/PCS code is entered on the claim.

Retroactive Coverage

Sterilization is covered by Medi-Cal only if all the applicable requirements are met at the time the operation is performed. If a patient obtains retroactive Medi-Cal coverage, previously provided sterilization services cannot be billed to Medi-Cal unless the applicable requirements have been met. If a patient receives a sterilization as a private patient and the provider later performs an eligibility verification transaction that proves the recipient has coverage for the month of service, the provider has no duty to bill the program unless all Medi-Cal requirements, including the signing of Consent Form (PM 330), were observed.
Anesthesia Time

Refer to the Anesthesia section in the appropriate Part 2 manual for instructions on billing for the anesthesia time associated with a tubal ligation.

Sterilization and Supplies Require Consent Forms

To comply with federal requirements, a legible copy of a valid sterilization Consent Form (PM 330) must accompany claims for sterilization services. This rule also extends to claims for supplies billed with modifiers UA or UB.

Codes Requiring Consent Forms

The following CPT and HCPCS codes require a sterilization Consent Form (PM 330) when the procedure will render the recipient sterile and unable to conceive.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>55250</td>
<td>Vasectomy, unilateral or bilateral, including postoperative semen examination(s)</td>
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<tr>
<td>58565</td>
<td>Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants</td>
</tr>
<tr>
<td>58600</td>
<td>Ligation or transection of fallopian tube(s), abdominal or vaginal approach, unilateral or bilateral</td>
</tr>
<tr>
<td>58605</td>
<td>Ligation or transection of fallopian tube(s), abdominal or vaginal approach, postpartum, unilateral or bilateral, during same hospitalization</td>
</tr>
<tr>
<td>58611</td>
<td>Ligation or transection of fallopian tube(s) when done at the time of cesarean delivery or intra-abdominal surgery</td>
</tr>
<tr>
<td>58615</td>
<td>Occlusion of fallopian tube(s) by device (e.g., band, clip, Falope ring) vaginal or suprapubic approach</td>
</tr>
<tr>
<td>58661</td>
<td>Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)</td>
</tr>
<tr>
<td>58670</td>
<td>Laparoscopy, surgical; with fulguration of oviducts (with or without transection)</td>
</tr>
<tr>
<td>58671</td>
<td>Laparoscopy, surgical; with occlusion of oviducts by device (e.g., band, clip, or Falope ring)</td>
</tr>
<tr>
<td>58700</td>
<td>Salpingectomy, complete or partial, unilateral or bilateral</td>
</tr>
<tr>
<td>58720</td>
<td>Salpingo-oophorectomy, complete or partial, unilateral or bilateral</td>
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<table>
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<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>A4264</td>
<td>Permanent implantable contraceptive intratubal occlusion device(s) and delivery system</td>
</tr>
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Part 2 – Sterilization
ICD-10-PCS Codes Identifying Sterilization Procedures

Sterilization services must be billed in conjunction with one of the following ICD-10-PCS codes:

- 0U550ZZ thru 0U578ZZ
- 0UB50ZX thru 0UB78ZZ
- 0UL50CZ thru 0UL78ZZ
- 0UT50ZZ thru 0UT7FZZ
- 0V5N0ZZ thru 0V5Q8ZZ
- 0VBN0ZZ
- 0VBN3ZZ
- 0VBN4ZZ
- 0VBN8ZZ
- 0VBP0ZZ
- 0VBP3ZZ
- 0VBP4ZZ
- 0VBP8ZX
- 0VBP8ZZ
- 0VBQ0ZZ
- 0VBQ3ZZ
- 0VBQ4ZZ
- 0VBQ8ZX
- 0VBQ8ZZ
- 0VLF0CZ thru 0VLF4ZZ
- 0VLF0CZ thru 0VLF4ZZ
- 0VLH0CZ thru 0VLH4ZZ
- 0VLN0CZ thru 0VLN8ZZ
- 0VLP0CZ thru 0VLP8ZZ
- 0VLP50ZZ thru 0VLP7FZZ
- 0VLQ0CZ thru 0VLQ8ZZ
- 0VTN0ZZ
- 0VTN4ZZ
- 0VTP0ZZ
- 0VTP4ZZ
- 0VTQ0ZZ
- 0VTQ4ZZ
- 0VLF0CZ thru 0VLF4ZZ
- 0VLP0CZ thru 0VLP8ZZ
- 0VLQ0CZ thru 0VLQ8ZZ
- 0VLN0CZ thru 0VLN8ZZ
- 0VLP50ZZ thru 0VLP7FZZ
- 0VLQ0CZ thru 0VLQ8ZZ
- 0VLN0CZ thru 0VLN8ZZ
- 0VLP50ZZ thru 0VLP7FZZ
- 0VLQ0CZ thru 0VLQ8ZZ
- 0VLN0CZ thru 0VLN8ZZ
- 0VLP50ZZ thru 0VLP7FZZ
- 0VLQ0CZ thru 0VLQ8ZZ
- 0VLN0CZ thru 0VLN8ZZ

Sterilization Consent Form Required

When a sterilization procedure is performed for the purpose of rendering the recipient sterile and unable to conceive, the provider must bill the sterilization code in conjunction with ICD-10-CM diagnosis code Z30.2 (encounter for sterilization) and enter the appropriate family planning code in the Condition Codes field (Boxes 18 thru 24) on the UB-04 claim or the EPSDT/Family Planning field (Box 24H) on the CMS-1500 claim. A completed sterilization Consent Form (PM 330) must be submitted for all elective sterilizations.

When CPT code 58661 (laparoscopy, surgical; with removal of adnexal structures [partial or total oophorectomy and/or salpingectomy]), 58700 (salpingectomy, complete or partial, unilateral or bilateral), 58720 (salpingo-oophorectomy, complete or partial unilateral or bilateral) or one of the following ICD-10-PCS codes 0U500ZZ thru 0U0524ZZ, 0U550ZZ thru 0U578ZZ, 0UB00ZX thru 0UB28ZZ, 0UB50ZX thru 0UB78ZZ, 0UT00ZZ thru 0UT2FZZ, 0UT50ZZ thru 0UT7FZZ (unilateral or bilateral destruction, excision or resection of fallopian tube and/or ovary) is performed for the purpose of rendering the recipient permanently incapable of reproducing, a PM 330 and an approved TAR are required.
Sterilization Consent Form Not Required
If a code is billed that requires a PM 330 but the surgery was not performed for the purpose of rendering the recipient permanently incapable of reproducing, then a PM 330 is not required. However, the claim will be denied unless at least one of the following justifications is present in the Remarks field (Box 80)/Additional Claim Information field (Box 19) of the claim or on an attachment:

- The surgery was a unilateral procedure and did not result in sterilization.
- The surgery was unilateral or bilateral but the patient was previously sterile. (On a signed attachment to the claim, the physician must explain the cause of the sterility.)
- The procedure was not elective and was done for an acute condition.

Exception: Claims for Essure-related CPT code 58565 and HCPCS code A4264 always require a PM 330.

Sterilization Services Inquiries
Questions concerning sterilization services covered by Medi-Cal should be directed to:

Medi-Cal Benefits Division
Department of Health Care Services
MS 4601
1501 Capitol Avenue, Suite 71.4001
P.O. Box 997417
Sacramento, CA 95899-7417
(916) 552-9797

Inquiries for Non-Medi-Cal Patients
Questions regarding sterilization service requirements for non-Medi-Cal patients should be addressed to:

Office of Family Planning
California Department of Health Care Services
MS 8400
1615 Capitol Avenue, Suite 73.430
P.O. Box 997413
Sacramento, CA 95899-7413
(916) 650-0414
Legend

Symbols used in the document above are explained in the following table.

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<thead>
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