

South Carolina Molina Clinical Policy - Sterilization

State(s):	South Carolina	Policy #:	SC_MCP_600 Sterilization
Lines of Business:	Medicaid	Original Effective Date:	7/10/2018
		MCPC Approved:	9/12/2024
Next Review Due:	September 2025	Review Date:	9/09/2024
		Revision Date:	9/09/2024

DISCLAIMER

This South Carolina Molina Clinical Policy (SC-MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this SC_MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Sterilization is a method of permanently preventing pregnancy by rendering the patient infertile. In women, sterilization is generally performed by tubal ligation or occlusion. In tubal sterilization, the fallopian tubes are cut and tied with special thread, closed shut with bands or clips, sealed with an electric current, or blocked with scar tissue formed by small implants. Tubal sterilization prevents the sperm from reaching the egg. Tubal sterilization can be performed with a Mini laparotomy, with laparoscopy, or with hysteroscopy. Salpingectomy refers to the surgical removal of a Fallopian tube and can be performed with laparotomy or laparoscopy.

Male sterilization (vasectomy) is a surgical procedure to cut or seal the tubes that carry a man's sperm (the vas deferens) are tied, sealed with heat, or clipped to permanently block sperm from leaving the male body and possibly causing pregnancy.

COVERAGE POLICY

Please check individual state health plan regulations and benefit contracts before applying this MCP. Coverage of female sterilization is applicable to individual State and Federal Health Plan Medicaid regulations and benefit contracts that supersede this policy. All State and Federal Health Plan eligibility requirements including any applicable consent forms must be met and completed.

South Carolina Department of Health and Human Services (SCDHHS) regulations on sterilization are defined below:

- Sterilization — Any medical procedure, treatment, or operation for the sole purpose of rendering an individual permanently incapable of reproducing
- **The Consent for Sterilization - SCDHHS form 687, is required for ALL procedures intended to result in sterilization.**
- **The Consent for Sterilization - SCDHHS form 687, is NOT required when a Hysterectomy is to be performed and prior sterilization has occurred.**
- Institutionalized Individual — An individual who is: Involuntarily confined or detained under a 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.

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- Mentally Incompetent Individual — Means an individual who has been declared mentally incompetent by a federal, state, or local court of competent jurisdiction for any purpose, unless the individual has been declared competent for purposes which include the ability to consent to sterilization.
- Sterilization Services:
 - Tubal ligation following a vaginal delivery by a method except laparoscope.
 - Tubal ligation following C-section or other intra-abdominal (tubal ligation as the minor procedure) surgery.
 - Ligation, transection of fallopian tubes; abdominal or vaginal approach.
 - Occlusion of fallopian tubes by device.
 - Laparoscopic sterilization by fulguration or cauterization.
 - Laparoscopic sterilization by occlusion by device.
 - Vasectomy

1) For an elective sterilization of an elective sterilization for a male or female, the following requirements must be met:

a) The Consent for Sterilization Form must be signed at least 30 days prior to, but no more than 180 days prior to, the scheduled date of sterilization.

i) All sections of the Sterilization Consent Form (SC-DHHS Form 687) must be completed when submitted with the for medical necessity review. Each Consent Form is reviewed for compliance with federal regulations (42 CFR 441.250–441.259 subpart F).

ii) If the beneficiary had an interpreter translate the consent form information into a foreign language (e.g., Spanish, French, etc.), the interpreter must complete this section. If an interpreter was not necessary, put "N/A" in these fields:

b) The member must be 21 years old at the time the Consent Form is signed.

c) The member cannot be institutionalized or mentally incompetent:

i) If the Physician questions the mental competency of the individual, he or she should contact the PSC at: +1 888 289 0709 or submit an online inquiry at: <https://www.scdhhs.gov/Contact-Info>.

d) The member must voluntarily give consent:

i) All questions must be answered and all topics in the Consent Form discussed. (A witness of the beneficiary's choice may be present during the consent interview.) The Family Planning counseling or Family Planning education/instruction procedure code may be billed when this service is rendered and documented.

e) Informed consent may not be obtained while the member is:

- i) In labor or childbirth.
- ii) Seeking or obtaining an abortion.
- iii) Under the influence of alcohol, controlled substances, or other substances which may affect the member's judgment.

2) Exceptions to the 30-Day Waiting Period:

a) **Premature Delivery:** The informed consent must have been signed at least 30 days prior to the expected date of delivery. In cases involving a Cesarean section, the scheduled date of the C-section is considered the expected date of delivery. At least 72 hours must have elapsed since the informed consent was given. Note: If the member is pregnant, premature delivery is the only exception to the 30-day waiting period.

b) **Emergency Abdominal Surgery:** The emergency does not include the operation to sterilize the beneficiary. At least 72 hours must have elapsed since the informed consent was given. An explanation must accompany the Consent Form.

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3) Essure Sterilization Procedure:

- a) SCDHHS will reimburse for the Essure Sterilization procedure only when certain criteria are met. b) This procedure is available to women who have risk factors that prevent a Physician from performing a safe and effective laparoscopic tubal ligation. Reimbursement will be provided for any of the following criteria:
- Morbid Obesity (BMI of 35 or greater).
 - Abdominal mesh that mechanically interferes with the laparoscopic tubal ligation.
 - Permanent colostomy.
 - Multiple abdominal/pelvic surgeries with documented severe adhesions.
 - Artificial heart valve requiring continuous anticoagulation.
 - Any severe medical problems that would contraindicate laparoscopy because of anesthesia considerations. (This must be attested in the request for prior approval that general anesthesia would pose a substantial threat to beneficiaries' life.)
- c) **A Consent for Sterilization Form must be completed and submitted with the claim.**

4) Non-Covered Services:

- a) Services beyond those outlined in this section that are required to manage or to treat medical conditions and/or diseases, whether such procedures are also related to Family Planning, are not covered under the Family Planning Program.

5) Note: Beneficiaries are allowed one permanent sterilization procedure per lifetime

END South Carolina Department of Health and Human Services (SCDHHS) regulations on sterilization

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

There is a moderate-sized body of evidence regarding salpingectomy for sterilization including randomized controlled trials, 3-4 a Cochrane review, 2 retrospective, comparative, and cohort studies. The published evidence is sufficient and generally supports salpingectomy has a means of permanent sterilization in women and is a safe and effective procedure.

A 2016 Cochrane Review compared the different tubal occlusion techniques in terms of major and minor morbidity, failure rates (pregnancies), technical failures and difficulties, and women's and surgeons' satisfaction (Lawrie et al. 2016). All RCTs comparing different techniques for tubal sterilization, irrespective of the route of fallopian tube access or the method of anesthesia were reviewed. 19 RCTs involving 13,209 women were included. Most studies concerned interval sterilization; three RCTs involving 1632 women, concerned postpartum sterilization. Comparisons included tubal rings versus clips (six RCTs, 4232 women); partial salpingectomy versus electrocoagulation (three RCTs, 2019 women); tubal rings versus electrocoagulation (two RCTs, 599 women); partial salpingectomy versus clips (four RCTs, 3627 women); clips versus electrocoagulation (two RCTs, 206 women); and Hulka versus Filshie clips (two RCTs, 2326 women). RCTs of clips versus electrocoagulation contributed no data to the review. One year after sterilization, failure rates were low (< 5/1000) for all methods. There were no deaths reported with any method, and major morbidity related to the occlusion technique was rare. Minor morbidity was higher with the tubal ring than the clip as were technical failures. Major morbidity was significantly higher with the modified Pomeroy technique than electrocoagulation, as was postoperative pain. When tubal rings were compared with electrocoagulation, postoperative pain was reported significantly more frequently for tubal rings. When partial salpingectomy was compared with clips, there were no major morbidity events in either group. The frequency of minor morbidity was low and not significantly different between groups. Although technical failure occurred more frequently with clips, operative time was shorter with clips than partial salpingectomy. We found little evidence concerning women's or surgeon's satisfaction. No RCTs compared tubal microinserts (hysteroscopic sterilization) or chemical inserts (quinacrine) to other methods. The review concluded that tubal sterilization by partial salpingectomy, electrocoagulation, or using clips or rings, is a safe and effective method of contraception. Failure rates at 12 months post-sterilization and major morbidity are rare outcomes with any of these techniques. Minor complications and technical failures appear to be more common with rings than clips. Electrocoagulation may be associated with less postoperative pain than the modified Pomeroy or tubal ring methods. Further research should include RCTs (for effectiveness) and controlled observational studies (for adverse effects) on sterilization by minimally-invasive methods, (i.e., tubal inserts and quinacrine).

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Ganer et al. (2017) compared short-term ovarian reserve and operative complications in cases of salpingectomy and tubal ligation during cesarean section. Study patients who underwent elective cesarean section at our institution and requested sterilization were randomized to bilateral salpingectomy or tubal ligation. Prior to surgery, blood samples were obtained for antimullerian hormone. Surgical course was noted, including overall time, complications, and postoperative hemoglobin. Repeat antimullerian hormone samples were obtained from patients 6-8 weeks following surgery. In all, 46 patients were recruited for participation, of whom 33 completed a follow-up visit, and for whom repeat antimullerian hormone levels were available. Patients in the salpingectomy group were slightly older (37.0 +/- 3.9 vs 34.3 +/- 4.1 years, P=0.02). No differences were noted in patient parity, body mass index, or gestational age between the groups. Pregnancy and post-delivery antimullerian hormone levels were not significantly different between the groups, with an average increase of 0.58 +/- 0.98 vs 0.39 +/- 0.41 ng/mL in the salpingectomy and tubal ligation groups, respectively (P =0.45). Surgeries including salpingectomy were longer by an average 13 minutes (66.0 +/- 20.5 vs 52.3 +/- 15.8 minutes, P =0.01). No difference was demonstrated between the groups regarding surgical complications and postoperative hemoglobin decrease. The authors concluded that sterilization by salpingectomy appears to be as safe as tubal ligation regarding operative complications and subsequent ovarian reserve. As salpingectomy offers the advantage of cancer risk reduction, it may be offered in the settings of elective preplanned surgeries.

Venturella et al. (2015) studied the effects of the wide excision of soft tissues adjacent to the ovary and fallopian tube on ovarian function and surgical outcomes in women undergoing laparoscopic bilateral prophylactic salpingectomy. One hundred eighty-six women were randomly divided into two groups. In group A (n = 91), standard salpingectomy was performed. In group B (n = 95), the mesosalpinx was removed within the tubes. Prior to and 3 months after surgery, antimullerian hormone (AMH), FSH, three-dimensional antral follicle count (AFC), vascular index (VI), flow index (FI), vascular-flow index (VFI), and OvAge were recorded for each patient. Ovarian reserve modification (Delta) before and after surgery was assessed as the primary outcome. Operative time, variation of the hemoglobin level (DeltaHb), postoperative hospital stays, postoperative return to normal activity, and complication rate were assessed as secondary outcomes. The results showed no significant difference between groups for DeltaAMH, DeltaFSH, DeltaAFC, DeltaVI, DeltaFI, DeltaVFI, and DeltaOvAge. Moreover, the groups were similar for operative time, DeltaHb, postoperative hospital stay, postoperative return to normal activity, and complication rate. In conclusion, even when the surgical excision includes the removal of the mesosalpinx, salpingectomy does not damage the ovarian reserve. Moreover, wide salpingectomy with excision of the mesosalpinx did not alter blood loss, hospitalization stay, or return to normal activities.

National and Specialty Organizations

American College of Obstetricians and Gynecologists (ACOG 2016) supports the following recommendations and conclusions based on the current understanding of ovarian carcinogenesis and the safety of salpingectomy:

- The surgeon and patient should discuss the potential benefits of the removal of the fallopian tubes during a hysterectomy in women at population risk of ovarian cancer who are not having an oophorectomy.
- When counseling women about laparoscopic sterilization methods, clinicians can communicate that bilateral salpingectomy can be considered a method that provides effective contraception.
- Prophylactic salpingectomy may offer clinicians the opportunity to prevent ovarian cancer in their patients.
- RCTs are needed to support the validity of this approach to reduce the incidence of ovarian cancer.
- The choice of sterilization procedure should be based on the risks and benefits of the hysteroscopic and laparoscopic approaches. If a laparoscopic approach is elected, then the risks and benefits of salpingectomy should be discussed.
- Other than a significant increase in operative time for salpingectomy with hysterectomy (16 minutes) and with sterilization (10 minutes), no significant differences in length of hospital stay, readmissions, or blood transfusions have been identified in cases with and without salpingectomy

CODING & BILLING INFORMATION

CPT Codes (Current Procedural Terminology) Code

Code	Description
58661	Laparoscopy, surgical: with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy) only

ICD (International Classification of Diseases)-10

Codes	Description
Z30.2	Encounter for sterilization
Z98.52	Vasectomy

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

REFERENCES

Peer Reviewed Publications

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National and Specialty Organizations

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- Salpingectomy for Ovarian Cancer Prevention. Committee Opinion. Number 620. Jan, 2015. Correction 2016. Accessed at: <https://www.acog.org/>
- Practice Bulletin No. 133, Obstetrics & Gynecology: February 2013 - Volume 121 - Issue 2 PART 1 - p 392-404 doi: 10.1097/01.AOG.0000426425.33845.b2

Other Peer Reviewed and Professional Organization Publications (used in the development of this policy)

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- Hayes a TractManager Company. Winifred Hayes Inc. Lansdale, PA.
- Salpingectomy for Primary Sterilization in Adults. September, 2017. [Archived Oct, 2018].

APPROVAL HISTORY

Revision	Review	MCP-Committee Approval Date	Comments
09/09/2024	09/09/24	9/12/2024	Updated with disclaimer (Footer)
	9/11/2023	9/11/2023	HCS Committee reviewed and approved
9/19/2022	9/19/2022	9/19/2022	Policy reviewed and updated against South Carolina Medicaid Policy and Procedure dated July 1, 2021, 2022 Provider Manual and MCG Criteria. New template adopted. Approved by D Enigl and Dr. Shrouds.
2/9/2022	2/9/2022	2/9/2022	State / MIH policy reviewed and updated, no changes in coverage position, updated references. New template.
2/8/2021	2/8/2021	2/8/2021	State / MHI Policy reviewed, no changes to criteria. References updated.
4/23/2020	4/23/2020	4/23/2020	State / MHI Policy reviewed, no changes to criteria. References updated.
9/18/2019	9/18/2019	9/18/2019	State / MHI Policy reviewed, no changes to criteria. References updated
7/10/2018	7/10/2018	7/10/2018	New Policy. IRO Peer Review: April 9, 2018. Policy reviewed by internal physician board certified in OB/GYN.
8/30/2023			Updated MCP for further clarification regarding required consents for sterilization/hysterectomy