

Subject: Salpingectomy for Female Sterilization		Original Effective Date: 7/10/2018
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

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 minilaparotomy, with laparoscopy, or with hysteroscopy. Salpingectomy refers to the surgical removal of a Fallopian tube and can be performed with laparotomy or laparoscopy.

RECOMMENDATION

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.

Medicare does not cover sterilization procedures unless it is medically necessary for the treatment of an illness or injury.¹

Bilateral Salpingectomy for female sterilization is considered medically necessary as an alternative to tubal ligation or occlusion of the fallopian tubes procedures in members who are 21 years of age and older.

SUMMARY OF MEDICAL EVIDENCE²⁻¹²

There is a moderate-sized body of evidence regarding salpingectomy for sterilization including randomized controlled trials (RCTs),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. All randomized controlled trials (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. ²

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. ³

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 stay, 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. ⁴

Professional Organizations ¹³⁻¹⁵

The American College of Obstetricians and Gynecologists (ACOG) ¹³ 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.
- Randomized controlled trials 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 INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy) only.
ICD-10	Description: [For dates of service on or after 10/01/2015]
Z30.2	Encounter for sterilization

RESOURCE REFERENCES

Government Agency

1. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National Coverage Determination (NCD) for Sterilization (230.3). Available at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>.

Peer Reviewed Literature

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5. Westberg J, Scott F, Creinin MD et al. Safety outcomes of female sterilization by salpingectomy and tubal occlusion. *Contraception*. 2017;May;95(5):505-508.
6. Dilley SE, Havrilesky LJ et al. Cost-effectiveness of opportunistic salpingectomy for ovarian cancer prevention. *Gynecol Oncol*. 2017;Aug;146(2):373-379.
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12. Powell CB, Alabaster A, Simmons S, et al. Salpingectomy for Sterilization: Change in Practice in a Large Integrated Health Care System, 2011-2016. *Obstet Gynecol* 2017; 130:961.

Professional Society Guidelines

13. American College of Obstetricians and Gynecologists (ACOG). Salpingectomy for Ovarian Cancer Prevention. Committee Opinion. Number 620. Jan, 2015. Correction 2016. Accessed at: <https://www.acog.org/>
14. American College of Obstetricians and Gynecologists. ACOG practice bulletin #133. Benefits and risks of sterilization. *Obstet Gynecol* 2013 Feb;121(2):392-404, reaffirmed 2015. Accessed at: https://journals.lww.com/greenjournal/Fulltext/2013/02000/Practice_Bulletin_No_133_Benefits_and_Risks_of.41.aspx
15. Centers for Disease Control and Prevention. U. S. selected practice recommendations for contraceptive use, 2016. *MMWR* 2016 Jul 29;65(3):1-104.

Other Resources

16. UpToDate: [website]. Waltham, MA: Walters Kluwer Health; 2019.
 - Braaten K. Postpartum sterilization. 2019.
 - Miller D. Opportunistic salpingectomy for ovarian, fallopian tubal, and peritoneal carcinoma risk reduction. 2019.
17. Hayes Search & Summary. Salpingectomy for Primary Sterilization in Adults. Winifred Hayes Inc. Lansdale, PA. September, 2017. Archived Oct, 2018.
18. Peer Review: Policy reviewed by internal physician board certified in OB/GYN, April 9, 2018.

Review/Revision History:

7/10/18: New Policy

9/18/19: Policy reviewed, no changes to criteria.