

BSC7.09 Hysterectomy Surgery for Benign Conditions			
Original Policy Date:	November 7, 2016	Effective Date:	April 1, 2025
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Policy Statement

Malignant Gynecologic Indications

- I. Hysterectomy for a gynecologic malignant or emergent condition may be considered **medically necessary** for **any** of the following conditions:
 - A. The presence, or the suspicion of, a malignancy must clearly be indicated as the preoperative reason
 - B. An emergent condition exists (e.g., ongoing heavy bleeding with a critically low hemoglobin level or unstable vital signs; postpartum hemorrhaging which cannot be controlled by conservative measures; uterine rupture during labor)

Non-malignant Gynecologic Indications

- II. Hysterectomy surgery for a gynecologic non-malignant or non-emergent condition may be considered **medically necessary** when the patient's procedure is for **any** of the following conditions:
 - A. Abnormal uterine bleeding (i.e., menorrhagia, hypermenorrhea) when **all** of the following criteria are met:
 1. No evidence of other pathology treatable by other means
 2. Endometrial sampling has been done and is negative for cancer or cannot be done (endometrial sampling is not required in a post-menopausal woman with ultrasound demonstrating an endometrial stripe of 4mm or less)
 3. Significant bleeding is recurrent in nature, affecting Activities of Daily Living (ADLs), and is on **either** of the following alternative treatments:
 - a. Unresponsive to hormonal therapy (i.e., progestones, estrogens, progestin intra-uterine device [IUD])
 - b. Unresponsive to endometrial ablation (or contraindicated)
 - B. High likelihood of adenomyosis in a parous woman, based on clinical examination and ultrasonographic or other radiologic evidence
 - C. Chronic Pelvic Inflammatory Disease (PID) which is clinically established as a diagnosis and unresponsive to conventional medical management, including tubo-ovarian abscess, either ruptured or unruptured, with insufficient clinical response to appropriate Intravenous (IV) antibiotic therapy or percutaneous drainage is not feasible
 - D. Endometriosis, when **all** the following criteria are met:
 1. Diagnosis of endometriosis is surgically confirmed
 2. Failure, intolerance or contraindication to hormone (i.e., birth control pills) or Gonadotropin-releasing hormone (GnRH) agonist therapy (i.e., Lupron)
 3. Disabling pelvic pain causing persistent impairment in Activities of Daily Living (ADLs)
 - E. Leiomyomata ([fibroid](#)) when **all** of the following criteria are met:
 1. Clinically significant symptoms, as indicated by **one or more** of the following:
 - a. Recurrent moderate to severe bleeding from a diagnosed uterine fibroid
 - b. Extra-uterine symptoms, including but not limited to bowel or bladder compression or dyspareunia
 2. Documentation of the presence of uterine leiomyomata by appropriate imaging
 3. Appropriate evaluation of the uterine lining:
 - a. For pre-menopausal women, pathologic assessment of the endometrium by **either** endometrial biopsy **or** dilation and curettage (D&C) in the setting of menometrorrhagia
 - b. Post-menopausal women that meets **either** of the following conditions:

- i. If endometrial stripe (lining) on uterine imaging is equal to or less than 4.0mm, endometrial biopsy is not required
 - ii. If endometrial stripe on uterine imaging is greater than 4.0mm, endometrial biopsy is required
 - F. Pelvic pain when **all** of the following criteria are met:
 - 1. No other treatable cause for the pain has been established after diligent clinical evaluation (including laparoscopy) and non-gynecological sources of pain (e.g., gastrointestinal, musculoskeletal, psychological, psychosexual, and/or urinary) have been excluded
 - 2. Pain symptoms interfere significantly with activities of daily living (ADLs) at least one or more days each month
 - 3. A conservative treatment (e.g., oral contraceptives, hormone-releasing IUDs, analgesics, non-steroidal medications, gonadotropin-releasing hormone [GnRH] analogs, Depo-Provera, physical therapy), have been unsuccessful or all are contraindicated
 - G. Pelvic relaxation (prolapse) when **both** of the following criteria are documented:
 - 1. Symptomatic uterine prolapse (second-degree or greater; cervix has descended to introitus or further)
 - 2. Failure or contraindication to, or individual non-acceptance of a nonsurgical option, such as the use of a pessary
 - H. Cervical Intraepithelial Neoplasia (CIN) when recurrent high-grade lesion (CIN 2 or CIN 3) is confirmed by biopsy after patient has had prior excisional or destructive therapy for CIN disease
 - I. Preventive gynecologic surgical intervention for a patient with **one or more** of the following:
 - 1. Hereditary nonpolyposis colorectal cancer (HNPCC) (i.e., Lynch Syndrome)
 - 2. *BRCA1 or BRCA2* positive status when an oophorectomy is performed at the same time
 - 3. Prophylactic ovarian surgery and patient elects to have uterus removed at the same time
- III. Hysterectomy is considered **not medically necessary** when the clinical indications are unclear or not adequately documented, including but not limited to confirmatory examination findings, laboratory results, and imaging studies.
- IV. The use of robotic surgical techniques is considered **not medically necessary** when separate payment is requested in addition to hysterectomy.

NOTE: Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Note: The policy statements refer only to surgical techniques utilized as a part of hysterectomy procedures. Other clinical applications of these techniques, such as hysterectomy and salpingo-oophorectomy, as applicable to genital reconstructive surgeries, are not addressed in this policy, but are outlined in Blue Shield of California Medical Policy: Gender Affirmation Surgery.

Note: In cases involving a small submucous fibroid (inside the uterus), hysteroscopic resection should be attempted prior to hysterectomy.

Coding

See the [Codes table](#) for details.

Description

Hysterectomy surgery is the surgical removal of the uterus, which may also involve the removal of the cervix, fallopian tubes, ovaries, and other surrounding structures. Usually performed by a gynecologist, hysterectomy may be total (removing the body, fundus, and cervix of the uterus; often called "complete") or partial (removal of the uterine body while leaving the cervix intact; also called "supracervical"). By removing the uterus, the patient is unable to have children (as does the removal of the ovaries and fallopian tubes) and has surgical risks as well as long-term effects, so the surgery is normally recommended when other treatment options are not available or have failed.²³

Related Policies

- Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids
- Magnetic Resonance-Guided Focused Ultrasound

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Hysterectomy surgical interventions are surgical procedures, therefore are not regulated by the U.S. Food and Drug Administration (FDA). However, on November 24, 2014, the FDA Safety Communications provided the updated Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy, warning against using laparoscopic power morcellators in the majority of women undergoing hysterectomy or myomectomy for uterine fibroids. Health care providers and patients should carefully consider available alternative treatment options for the removal of symptomatic uterine fibroids.²

The FDA recommends the following for Health Care Providers²:

- Be aware of the following new contraindications recommended by the FDA;
 - Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are peri- or post-menopausal, or are candidates for en bloc tissue removal, for example through the vagina or mini-laparotomy incision. (Note: These groups of women represent the majority of women with fibroids who undergo hysterectomy and myomectomy.)
 - Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.
- Be aware of the following new boxed warning recommended by the FDA:
The FDA warns that uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.
- Carefully consider all the available treatment options for women with uterine fibroids.

Thoroughly discuss the benefits and risks of all treatments with patients. Be certain to inform the small group of patients for whom laparoscopic power morcellation may be an acceptable therapeutic option that their fibroid(s) may contain unexpected cancerous tissue and that laparoscopic power morcellation may spread the cancer, significantly worsening their prognosis. This population might include some younger women who want to maintain their fertility or women not yet peri-menopausal who wish to keep their uterus after being informed of the risks.

Rationale

Background

Hysterectomy is considered throughout the policy as a definitive surgical treatment for those who no longer will maintain fertility.

Hysterectomy is the most commonly performed gynecological surgical procedure. There are broad diagnostic categories of indications for hysterectomy, including, but not limited to the following:

- Abnormal uterine bleeding
- Leiomyomata
- Pelvic cancers (e.g., endometrial cancer, cervical cancer, ovarian cancer)
- Pelvic organ prolapse
- Pelvic pain

Surgical Procedures

Total Abdominal Hysterectomy (TAH) describes the most commonly performed hysterectomy procedure in which the uterine fundus is removed. It may be performed through either a transverse or vertical abdominal incision. This is the preferred procedure where evaluation of the entire pelvis is necessary, and conservation of the cervix is not desired.

Vaginal Hysterectomy (VH) is performed entirely through the vagina when the exploration of the upper pelvic area is not required. The most common conditions for this procedure include uterine prolapse.

Radical Hysterectomy (RH) involves the removal of the parametrial tissue and the upper vagina in conjunction with the uterine fundus and cervix and includes lymph node sampling. The ovaries and fallopian tubes are often removed as well. This procedure is most commonly performed in the treatment of gynecologic cancers. Complications could include bladder and bowel dysfunction, and ureteral injury.

Supracervical Hysterectomy (SH) can be performed abdominally or vaginally and is the preferred procedure when conservation of the cervix is desired. The fundus of the uterus is removed below the level of the uterine vessels and the cervix is left intact.

Laparoscopic hysterectomy is a general term referring to a spectrum of procedures that differ in the proportion of the hysterectomy that is performed laparoscopically, and the proportion performed by vaginal techniques. The technical difficulty of the procedure increases as more components of the operation are performed under laparoscopic guidance. With the exception of laparoscopic radical hysterectomy, laparoscopic approaches are considered alternatives to abdominal hysterectomies, due to the lower morbidity associated with the minimal abdominal incisions and handling of the bowel. However, these advantages may not apply to those patients who would be considered for conventional vaginal hysterectomies.

In general, laparoscopic hysterectomy approaches can be subdivided into the following categories:

1. Entire procedure performed laparoscopically:

Total laparoscopic hysterectomy (TLH) describes a procedure in which the entire uterus and cervix are dissected under laparoscopic guidance and then morcellated and removed through a small abdominal incision.

Laparoscopically assisted supracervical hysterectomy (LSH, LASH) describes a procedure in which the entire dissection is done laparoscopically, however the uterus is amputated supracervically, and the specimen is morcellated and removed through a small incision, typically at the umbilicus.

2. Procedure performed laparoscopically and vaginally:

Laparoscopic hysterectomy (LH) describes a procedure in which all the major vascular pedicles, including the uterine vessels, are secured by laparoscopic techniques but the vaginal vault and supporting ligaments are secured vaginally.

Laparoscopically assisted vaginal hysterectomy (LAVH) describes a procedure in which only the adnexa and upper uterine pedicles and the bladder flap are dealt with laparoscopically. The uterus is removed through a vaginal incision.

Laparoscopic radical hysterectomy (LRH) describes surgery to remove the uterus, cervix, and part of the vagina that is done under laparoscopic guidance. The ovaries, fallopian tubes, and nearby lymph nodes may also be removed.

This policy relates to hysterectomy, or complete or supra-cervical uterine removal, performed using vaginal or abdominal approaches, with or without laparoscopic or robotic assistance, or performed exclusively by laparoscopy, for patients with pre-malignant, malignant, or benign conditions. The procedure may or may not include salpingo-oophorectomy.

Literature Review**Non-malignant Gynecologic Indications**

The three approaches to hysterectomy for benign disease are abdominal hysterectomy (AH), vaginal hysterectomy (VH), and laparoscopic hysterectomy (LH). Laparoscopic hysterectomy has three further subdivisions depending on the part of the procedure performed laparoscopically. Nieboer TE, et al searched the Cochrane Menstrual Disorders and Subfertility Group Specialized Register of controlled trials (15 August 2008), CENTRAL (The Cochrane Library 2008, Issue 3), MEDLINE (1950 to August 2008), EMBASE (1980 to August 2008), Biological Abstracts (1969 to August 2008), the National Research Register, and relevant citation lists. Only randomized controlled trials comparing one surgical approach to hysterectomy with another were included. Independent selection of trials and data extraction were employed following Cochrane guidelines and there were 34 included studies with 4495 women. The benefits of VH versus AH were speedier return to normal activities (mean difference (MD) 9.5 days), fewer febrile episodes or unspecified infections (odds ratio (OR) 0.42), and shorter duration of hospital stay (MD 1.1 days). The benefits of LH versus AH were speedier return to normal activities (MD 13.6 days), lower intraoperative blood loss (MD 45 cc), a smaller drop in hemoglobin (MD 0.55 g/dl), shorter hospital stay (MD 2.0 days), and fewer wound or abdominal wall infections (OR 0.31) at the cost of more urinary tract (bladder or ureter) injuries (OR 2.41) and longer operation time (MD 20.3 minutes). The benefits of LAVH versus TLH were fewer febrile episodes or unspecified infection (OR 3.77) and shorter operation time (MD 25.3 minutes). There was no evidence of benefits of LH versus VH and the operation time (MD 39.3 minutes) as well as substantial bleeding (OR 2.76) were increased in LH. For some important outcomes, the analyses were underpowered to detect important differences, or they were simply not reported in trials. Data were absent for many important long-term outcome measures. The authors concluded that because of equal or significantly better outcomes on all parameters, VH should be performed in preference to AH where possible. Where VH is not possible, LH may avoid the need for AH however the length of the surgery increases as the extent of the surgery performed laparoscopically increases. The surgical approach to hysterectomy should be decided by the woman in discussion with her surgeon in light of the relative benefits and hazards.²⁷

Sarlos et al (2012) conducted a randomized controlled trial (RCT) where patients with benign indications for hysterectomy were randomized to receive either a robotic (robotic group) or conventional laparoscopic hysterectomy (conventional group). The primary end point was total operating time; secondary end points were perioperative outcome, blood loss, and the change in quality of life. Ninety-five patients out of 100 randomized patients completed the study. Patient age, body mass index, and uterus weight showed no significant differences between both groups. All results are given as mean (\pm standard deviation; median). Total operating time for the robotic group was significantly higher with 106 (\pm 29; 103) compared with 75 (\pm 21; 74) (conventional group) minutes. Blood loss, complications, analgesics use, and return to activity for both groups were comparable. The change in preoperative to postoperative quality-of-life index (quality of life measured on a linear scale from 0 to 100) was significantly higher in the robotic group, with 13 (\pm 10; 13) compared with 5 (\pm 14; 5) (conventional group). This RCT concluded that Robot-assisted laparoscopic hysterectomy and conventional laparoscopy compare well in most surgical aspects, but the robotic procedure is associated with longer operating times. Postoperative quality-of-life index was better; however, long-term, there was no difference. However, subjective postoperative parameters such as analgesic use and return to activity showed no significant difference between both groups.²⁸

Wright et al. (2013) conducted a large population-based retrospective cohort study, including data from 441 hospitals. The authors analyzed the uptake of robotically assisted hysterectomy (RAH) and compared RAH with LH in terms of intraoperative complications. They found that patients who underwent RAH were less likely to spend greater than 2 days in the hospital (19.6% versus 24.9%; relative risk [RR]=0.78; 95% CI: 0.67-0.92) but found no difference in complication rates between patients who underwent RAH and conventional LH (5.5% versus 5.3%; RR=1.03; 95% CI: 0.86-1.24), and no difference between the groups in terms of transfusion requirements (1.4% versus 1.8%; RR=0.80; 95% CI: 0.55-1.16).²⁹

Rosero et al. (2013) also conducted a large population-based retrospective cohort study. The study used the Nationwide Inpatient Sample, which is the largest publicly available, all-payer, inpatient care database in the U.S. and included data from greater than 1000 hospitals. Similar to the study by Wright and colleagues, Rosero et al. found similar overall complications rates between RAH and conventional LH (8.8% versus 8.85%, respectively; RR=0.99; 95% CI: 0.89-1.09). Patients undergoing RAH were less likely to require a blood transfusion (2.12% versus 3.13%; RR=0.67; 95% CI: 0.55-0.82) but more likely to suffer pneumonia following surgery (0.5% versus 0.23%; RR=2.2; 95% CI: 1.24-3.78).³⁰

The remainder of the current literature consists of single-institution studies of low-to-moderate quality that compare robotic hysterectomy with abdominal and laparoscopic approaches. These studies show no significant difference in mean operating time or perioperative morbidity compared with traditional laparoscopic procedures. However, compared with laparotomy, robot-assisted approaches had less blood loss, lower complication rates, and shorter hospital stays. Concern has arisen that vaginal cuff dehiscence may be more likely with robotic-assisted hysterectomy. The overall incidence of vaginal cuff dehiscence after any hysterectomy is 0.14–4.1%; however, a recent large cohort study suggested that transvaginal closure of the cuff was associated with a threefold and nine fold reduction in the risk of dehiscence compared with laparoscopic and robotic closure, respectively.³¹

Overall, the current literature shows conflicting evidence and is of poor quality. Based on RCTs and two large cohort studies, robot-assisted hysterectomy appears to have similar morbidity profiles to laparoscopic procedures but results in significantly higher costs. Further comparative studies that assess long-term outcomes and patient safety and identify subgroups of patients who would benefit from a robotic approach are warranted. Reporting of adverse events is currently voluntary and unstandardized, and the true rate of complications is not known. American Congress of Obstetricians and Gynecologists (ACOG) and Society of Gynecologic Surgeons (SGS) recommend the development

of a registry of robot-assisted gynecologic procedures and the use of the Manufacturer and User Facility Device Experience Database to report adverse events. Additionally, based on its well-documented advantages and lower complication rates, ACOG continues to recommend vaginal hysterectomy as the approach of choice for benign disease whenever feasible.^{17,31}

Malignant or Pre-Malignant Gynecologic Indications

Massad LS, et al updated consensus guidelines for the management of abnormal cervical cancer screening tests and cancer precursors. A group of 47 experts representing 23 professional societies, national and international health organizations, and federal agencies met in Bethesda, MD, September 14-15, 2012, to revise the 2006 American Society for Colposcopy and Cervical Pathology Consensus Guidelines. The group's goal was to provide revised evidence-based consensus guidelines for managing women with abnormal cervical cancer screening tests, cervical intraepithelial neoplasia (CIN) and adenocarcinoma in situ (AIS) following adoption of cervical cancer screening guidelines incorporating longer screening intervals and co-testing. In addition to literature review, data from almost 1.4 million women in the Kaiser Permanente Northern California Medical Care Plan provided evidence on risk after abnormal tests. Where data were available, guidelines prescribed similar management for women with similar risks for CIN 3, AIS, and cancer. Most prior guidelines were reaffirmed. Examples of updates include: Human papillomavirus-negative atypical squamous cells of undetermined significance results are followed with co-testing at 3 years before return to routine screening and are not sufficient for exiting women from screening at age 65 years; women aged 21-24 years need less invasive management, especially for minor abnormalities; post-colposcopy management strategies incorporate co-testing; endocervical sampling reported as CIN 1 should be managed as CIN 1; unsatisfactory cytology should be repeated in most circumstances, even when HPV results from co-testing are known, while most cases of negative cytology with absent or insufficient endocervical cells or transformation zone component can be managed without intensive follow-up.²⁴

Lynch syndrome (LS) is characterized by the development of colorectal cancer, endometrial cancer and various other cancers, and is caused by a mutation in one of the mismatch repair genes: MLH1, MSH2, MSH6 or PMS2. Vasen HF, et al reported that in 2007, a group of European experts (the Mallorca group) published guidelines for the clinical management of LS. Since then substantial new information has become available necessitating an update of the guidelines. In 2011 and 2012 workshops were organized in Palma de Mallorca. A total of 35 specialists from 13 countries participated in the meetings. The first step was to formulate important clinical questions. Then a systematic literature search was performed using the PubMed database and manual searches of relevant articles. During the workshops the outcome of the literature search was discussed in detail. Prospective controlled studies should be undertaken to improve further the care of these families.²⁵

Zullo F et al reported that there was a search conducted in 2012 for randomized controlled trials that reported data from women with histologically confirmed endometrial cancer who underwent laparoscopic or abdominal surgery. An additional meta-analysis was performed, and the primary endpoints were the rates of intraoperative and postoperative complications. A total of 8 original randomized controlled trials were included in the final analysis. No significant difference was observed in the relative risk (RR) for intraoperative complications between laparoscopy and laparotomy (RR, 1.25; 95% confidence interval: 0.99-1.56; P = .062). In contrast, a significant advantage of laparoscopy over laparotomy was obtained in terms of postoperative complications (RR, 0.71; 95% confidence interval: 0.63-0.79; P = .016). In comparison with abdominal surgery, the safety of the laparoscopic approach for surgical staging of endometrial cancer is similar in terms of intraoperative complications but results in fewer postoperative complications.²⁶

Outcomes and Complication Rates

Evidence demonstrates that, in general, vaginal hysterectomy is associated with better outcomes and fewer complications. A Cochrane review of 34 randomized trials of abdominal hysterectomy, laparoscopic hysterectomy, and vaginal hysterectomy, including 4,495 patients, concluded that

vaginal hysterectomy has the best outcomes of these three routes. The review also found that when a vaginal hysterectomy is not possible, laparoscopic hysterectomy has advantages (including faster return to normal activity, shorter duration of hospital stays, lower intraoperative blood loss, and fewer wound infections) over abdominal hysterectomy; however, laparoscopic surgery also is associated with longer operating time and higher rates of urinary tract injury.^{17,27}

Summary

The American Congress of Obstetricians and Gynecologists (ACOG) cites hysterectomy surgery as "One of the most frequently performed surgical procedures in the US...approximately 600,000 hysterectomies are performed each year." The traditional medical indications for hysterectomy are multiple and complex, but advances in safe, less invasive therapies for common gynecologic indications often make this type of major surgery, with its attendant risks to patients, unnecessary. The first reason for this Blue Shield of California surgical policy is to promote these advances in alternative therapies for women's health conditions by making their prior use (where appropriate) a criterion for payment of any subsequent hysterectomy procedure, and to assure the member has documented her knowledge of these therapies and has affirmed her active role in decision-making for their use.

The second reason for the policy concerns informed decision-making about the route of the hysterectomy to be performed. Although ACOG, in its 2009 position paper, recommends vaginal hysterectomy as "the safest and most cost-effective method to remove the uterus for non-cancerous reasons," it is clear that other factors may properly influence the specific route of hysterectomy procedure ultimately used. The physician's and the member's choice of hysterectomy surgery (abdominal, laparoscopic, or vaginal, any of these with or without robotic or laparoscopic assistance) certainly depends on the specific patient's symptoms, extra-uterine disease, physical/imaging findings and the need for ancillary procedures, but other factors, such as the informed member's preference, facility capabilities, and the expertise of the surgeon may play an appropriate role in decision-making. The policy is designed to assure the surgeon's consideration of these factors and presentation of them to the patient, and the member's ultimate informed agreement to the type of procedure to be performed.

Supplemental Information

Position and Policy Statements

American College of Obstetricians and Gynecologists: The American College of Obstetricians and Gynecologists (ACOG) guidelines were published in 2009 and reaffirmed in 2011; Single-Incision Laparoscopic Surgery (SILS) is not specifically addressed. ACOG considers vaginal hysterectomy the approach of choice for hysterectomy whenever feasible. When vaginal hysterectomy is not possible, laparoscopic hysterectomy offers faster return to normal activity, shorter hospital length of stay (HLOS), lower intraoperative blood loss, and fewer wound infections compared with abdominal hysterectomy. However, laparoscopic surgery is also associated with longer operating times and higher rates of urinary tract injury (ACOG, 2009).¹⁷

American College of Obstetricians and Gynecologists: The American College of Obstetricians and Gynecologists (ACOG) committee opinion regarding the role of transvaginal ultrasonography in the evaluation of postmenopausal bleeding was published in 2009 and reaffirmed in 2015.³² Endometrial tissue sampling resulting in findings insufficient for diagnosis is common. In a study of 97 consecutive patients with postmenopausal bleeding evaluated by transvaginal ultrasonography and endometrial biopsy, in only 82% of the patients with an endometrial thickness of less than 5 mm (n=45) was a Pipelle biopsy able to be performed (10). Of these patients, a sample adequate for diagnosis was obtained in only 27%. There was no correlation with parity or cavity length. In other studies of patients with postmenopausal bleeding, the range of sampling failure (i.e., inadequate sample or inability to perform the biopsy) with Pipelle biopsy was 0–54%.³³

Transvaginal ultrasonography can be useful in the triage of patients in whom endometrial sampling was performed but tissue was insufficient for diagnosis.³⁴ No further evaluation is necessary following an insufficient endometrial biopsy if subsequent transvaginal ultrasonography demonstrates an endometrial thickness of less than or equal to 4 mm in a woman with postmenopausal bleeding because the incidence of malignancy is rare in these cases (Table 1). However, if bleeding recurs or persists, additional evaluation usually is indicated.

Table 1. Endometrial Thickness and Cancer Findings in Postmenopausal Women with Bleeding

Reference	Endometrial Thickness*	Number of Women	Number of Cases of Cancer	Negative Predictive Value
Karlsson 1995 ^t	≤4 mm	1,168	0	100%
Ferrazzi 1996 [‡]	≤4 mm	930	2	99.8%
	≤5 mm		4	99.6%
Gull 2000 [§]	≤4 mm	163	1	99.4%
Epstein 2001	≤5 mm	97	0	100%
Gull 2003 [¶]	≤4 mm	394	0	100%

*Determined by transvaginal ultrasonography

^tKarlsson B, Granberg S, Wikland M, Ylostalo P, Torvid K, Marsal K, et al. Transvaginal ultrasonography of the endometrium in women with postmenopausal bleeding---a Nordic multicenter study. *Am J Obstet Gynecol* 1995;172:1488-94.

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^{||}Epstein E, Valentin L. Rebleeding and endometrial growth in women with postmenopausal bleeding and endometrial thickness < 5 mm managed by dilatation and curettage or ultrasound follow-up: a randomized controlled study. *Ultrasound Obstet Gynecol* 2001;18:499-504.

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Society of Obstetricians and Gynaecologists of Canada: Society of Obstetricians and Gynaecologists of Canada (SOGC) guidelines do not specifically address SILS. SOGC considers the vaginal route the first choice for all benign indications for hysterectomy. The laparoscopic approach should be considered when it reduces the need for a laparotomy.¹⁸

American Association of Gynecologic Laparoscopists: The American Association of Gynecologic Laparoscopists (AAGL) position statement on the route of hysterectomy for benign uterine disease does not specifically address SILS, but states that most hysterectomies for benign disease should be performed either vaginally or laparoscopically and that both routes can be safely used as outpatient procedures. When vaginal hysterectomy is not feasible, laparoscopic hysterectomy is a safe alternative that preserves most of the advantages of vaginal over abdominal hysterectomy.¹⁹

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
 - Reason for surgical intervention (malignant or non-malignant indications such as abnormal uterine bleeding, adenomyosis, pain, etc.)
- Prior conservative treatments, duration, and response including but not limited to those the patient:
 - Has tried (and results)
 - Has not tolerated
 - Has a contraindication to
 - Has declined (Note: If the patient has declined less invasive alternatives to hysterectomy the rationale must be documented.)
- Past and present diagnostic testing and results
- Pertinent past procedural and surgical history
- Radiology report(s) (i.e., MRI, CT, US)

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	51925	Closure of vesicouterine fistula; with hysterectomy
	58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)
	58152	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s); with colpo-urethrocystopexy (e.g., Marshall-Marchetti-Krantz, Burch)
	58180	Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)
	58200	Total abdominal hysterectomy, including partial vaginectomy, with para-aortic and pelvic lymph node sampling, with or without removal of tube(s), with or without removal of ovary(s)
	58210	Radical abdominal hysterectomy, with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy), with or without removal of tube(s), with or without removal of ovary(s)
	58240	Pelvic exenteration for gynecologic malignancy, with total abdominal hysterectomy or cervicectomy, with or without removal of tube(s), with or without removal of ovary(s), with removal of bladder and ureteral transplantations, and/or abdominoperineal resection of rectum and colon and colostomy, or any combination thereof
	58260	Vaginal hysterectomy, for uterus 250 g or less;
	58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
	58263	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s), with repair of enterocele
	58267	Vaginal hysterectomy, for uterus 250 g or less; with colpo-urethrocystopexy (Marshall-Marchetti-Krantz type, Pereyra type) with or without endoscopic control
	58270	Vaginal hysterectomy, for uterus 250 g or less; with repair of enterocele
	58275	Vaginal hysterectomy, with total or partial vaginectomy
	58280	Vaginal hysterectomy, with total or partial vaginectomy; with repair of enterocele
	58285	Vaginal hysterectomy, radical (schauta type operation)
	58290	Vaginal hysterectomy, for uterus greater than 250 g
	58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)

Type	Code	Description
	58292	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s), with repair of enterocele
	58294	Vaginal hysterectomy, for uterus greater than 250 g; with repair of enterocele
	58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less
	58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
	58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g
	58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
	58548	Laparoscopy, surgical, with radical hysterectomy, with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy), with removal of tube(s) and ovary(s), if performed
	58550	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less
	58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
	58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g
	58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
	58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less
	58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
	58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g
	58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
	58951	Resection (initial) of ovarian, tubal or primary peritoneal malignancy with bilateral salpingo-oophorectomy and omentectomy; with total abdominal hysterectomy, pelvic and limited para-aortic lymphadenectomy
	58953	Bilateral salpingo-oophorectomy with omentectomy, total abdominal hysterectomy and radical dissection for debulking
	58954	Bilateral salpingo-oophorectomy with omentectomy, total abdominal hysterectomy and radical dissection for debulking; with pelvic lymphadenectomy and limited para-aortic lymphadenectomy
	58956	Bilateral salpingo-oophorectomy with total omentectomy, total abdominal hysterectomy for malignancy
	59525	Subtotal or total hysterectomy after cesarean delivery (List separately in addition to code for primary procedure)
HCCPS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
11/07/2016	Custom Policy
03/01/2017	Policy revision without position change
08/01/2017	Policy revision without position change
10/01/2017	Policy title change from Hysterectomy Surgery Policy revision without position change
12/01/2017	Policy revision without position change
02/01/2018	Policy revision without position change
05/01/2018	Policy revision without position change
05/01/2019	Policy revision without position change
04/01/2020	Administrative update. Policy statement and guidelines updated.
05/01/2020	Annual review. Policy statement, guidelines and literature updated.
01/01/2021	Coding Update
05/01/2021	Annual review. No change to policy statement.
05/01/2022	Annual review. No change to policy statement.
12/01/2022	Administrative update. Policy statement, guidelines and literature updated.
04/01/2023	Annual review. No change to policy statement.
04/01/2024	Annual review. No change to policy statement.
04/01/2025	Annual review. No change to policy statement.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p>Hysterectomy Surgery for Benign Conditions BSC7.09</p> <p>Policy Statement: Malignant Gynecologic Indications</p> <ol style="list-style-type: none"> I. Hysterectomy for a gynecologic malignant or emergent condition may be considered medically necessary for any of the following conditions: <ol style="list-style-type: none"> A. The presence, or the suspicion of, a malignancy must clearly be indicated as the preoperative reason B. An emergent condition exists (e.g., ongoing heavy bleeding with a critically low hemoglobin level or unstable vital signs; postpartum hemorrhaging which cannot be controlled by conservative measures; uterine rupture during labor) <p>Non-malignant Gynecologic Indications</p> <ol style="list-style-type: none"> II. Hysterectomy surgery for a gynecologic non-malignant or non-emergent condition may be considered medically necessary when the patient's procedure is for any of the following conditions: <ol style="list-style-type: none"> A. Abnormal uterine bleeding (i.e., menorrhagia, hypermenorrhea) when all of the following criteria are met: <ol style="list-style-type: none"> 1. No evidence of other pathology treatable by other means 2. Endometrial sampling has been done and is negative for cancer or cannot be done (endometrial sampling is not required in a post-menopausal woman with ultrasound demonstrating an endometrial stripe of 4mm or less) 3. Significant bleeding is recurrent in nature, affecting Activities of Daily Living (ADLs), and is on either of the following alternative treatments: <ol style="list-style-type: none"> a. Unresponsive to hormonal therapy (i.e., progesterones, estrogens, progestin intra-uterine device [IUD]) b. Unresponsive to endometrial ablation (or contraindicated) 	<p>Hysterectomy Surgery for Benign Conditions BSC7.09</p> <p>Policy Statement: Malignant Gynecologic Indications</p> <ol style="list-style-type: none"> I. Hysterectomy for a gynecologic malignant or emergent condition may be considered medically necessary for any of the following conditions: <ol style="list-style-type: none"> A. The presence, or the suspicion of, a malignancy must clearly be indicated as the preoperative reason B. An emergent condition exists (e.g., ongoing heavy bleeding with a critically low hemoglobin level or unstable vital signs; postpartum hemorrhaging which cannot be controlled by conservative measures; uterine rupture during labor) <p>Non-malignant Gynecologic Indications</p> <ol style="list-style-type: none"> II. Hysterectomy surgery for a gynecologic non-malignant or non-emergent condition may be considered medically necessary when the patient's procedure is for any of the following conditions: <ol style="list-style-type: none"> A. Abnormal uterine bleeding (i.e., menorrhagia, hypermenorrhea) when all of the following criteria are met: <ol style="list-style-type: none"> 1. No evidence of other pathology treatable by other means 2. Endometrial sampling has been done and is negative for cancer or cannot be done (endometrial sampling is not required in a post-menopausal woman with ultrasound demonstrating an endometrial stripe of 4mm or less) 3. Significant bleeding is recurrent in nature, affecting Activities of Daily Living (ADLs), and is on either of the following alternative treatments: <ol style="list-style-type: none"> a. Unresponsive to hormonal therapy (i.e., progesterones, estrogens, progestin intra-uterine device [IUD]) b. Unresponsive to endometrial ablation (or contraindicated)

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p>B. High likelihood of adenomyosis in a parous woman, based on clinical examination and ultrasonographic or other radiologic evidence</p> <p>C. Chronic Pelvic Inflammatory Disease (PID) which is clinically established as a diagnosis and unresponsive to conventional medical management, including tubo-ovarian abscess, either ruptured or unruptured, with insufficient clinical response to appropriate Intravenous (IV) antibiotic therapy or percutaneous drainage is not feasible</p> <p>D. Endometriosis, when all the following criteria are met:</p> <ol style="list-style-type: none"> 1. Diagnosis of endometriosis is surgically confirmed 2. Failure, intolerance or contraindication to hormone (i.e., birth control pills) or Gonadotropin-releasing hormone (GnRH) agonist therapy (i.e., Lupron) 3. Disabling pelvic pain causing persistent impairment in Activities of Daily Living (ADLs) <p>E. Leiomyomata (fibroid) when all of the following criteria are met:</p> <ol style="list-style-type: none"> 1. Clinically significant symptoms, as indicated by one or more of the following: <ol style="list-style-type: none"> a. Recurrent moderate to severe bleeding from a diagnosed uterine fibroid b. Extra-uterine symptoms, including but not limited to bowel or bladder compression or dyspareunia 2. Documentation of the presence of uterine leiomyomata by appropriate imaging 3. Appropriate evaluation of the uterine lining: <ol style="list-style-type: none"> a. For pre-menopausal women, pathologic assessment of the endometrium by either endometrial biopsy or dilation and curettage (D&C) in the setting of menometrorrhagia b. Post-menopausal women that meets either of the following conditions: <ol style="list-style-type: none"> i. If endometrial stripe (lining) on uterine imaging is equal to or less than 4.0mm, endometrial biopsy is not required 	<p>B. High likelihood of adenomyosis in a parous woman, based on clinical examination and ultrasonographic or other radiologic evidence</p> <p>C. Chronic Pelvic Inflammatory Disease (PID) which is clinically established as a diagnosis and unresponsive to conventional medical management, including tubo-ovarian abscess, either ruptured or unruptured, with insufficient clinical response to appropriate Intravenous (IV) antibiotic therapy or percutaneous drainage is not feasible</p> <p>D. Endometriosis, when all the following criteria are met:</p> <ol style="list-style-type: none"> 1. Diagnosis of endometriosis is surgically confirmed 2. Failure, intolerance or contraindication to hormone (i.e., birth control pills) or Gonadotropin-releasing hormone (GnRH) agonist therapy (i.e., Lupron) 3. Disabling pelvic pain causing persistent impairment in Activities of Daily Living (ADLs) <p>E. Leiomyomata (fibroid) when all of the following criteria are met:</p> <ol style="list-style-type: none"> 1. Clinically significant symptoms, as indicated by one or more of the following: <ol style="list-style-type: none"> a. Recurrent moderate to severe bleeding from a diagnosed uterine fibroid b. Extra-uterine symptoms, including but not limited to bowel or bladder compression or dyspareunia 2. Documentation of the presence of uterine leiomyomata by appropriate imaging 3. Appropriate evaluation of the uterine lining: <ol style="list-style-type: none"> a. For pre-menopausal women, pathologic assessment of the endometrium by either endometrial biopsy or dilation and curettage (D&C) in the setting of menometrorrhagia b. Post-menopausal women that meets either of the following conditions: <ol style="list-style-type: none"> i. If endometrial stripe (lining) on uterine imaging is equal to or less than 4.0mm, endometrial biopsy is not required

POLICY STATEMENT

(No changes)

BEFORE	AFTER
<p>ii. If endometrial stripe on uterine imaging is greater than 4.0mm, endometrial biopsy is required</p> <p>F. Pelvic pain when all of the following criteria are met:</p> <ol style="list-style-type: none"> 1. No other treatable cause for the pain has been established after diligent clinical evaluation (including laparoscopy) and non-gynecological sources of pain (e.g., gastrointestinal, musculoskeletal, psychological, psychosexual, and/or urinary) have been excluded 2. Pain symptoms interfere significantly with activities of daily living (ADLs) at least one or more days each month 3. A conservative treatment (e.g., oral contraceptives, hormone-releasing IUDs, analgesics, non-steroidal medications, gonadotropin-releasing hormone [GnRH] analogs, Depo-Provera, physical therapy), have been unsuccessful or all are contraindicated <p>G. Pelvic relaxation (prolapse) when both of the following criteria are documented:</p> <ol style="list-style-type: none"> 1. Symptomatic uterine prolapse (second-degree or greater; cervix has descended to introitus or further) 2. Failure or contraindication to, or individual non-acceptance of a nonsurgical option, such as the use of a pessary <p>H. Cervical Intraepithelial Neoplasia (CIN) when recurrent high-grade lesion (CIN 2 or CIN 3) is confirmed by biopsy after patient has had prior excisional or destructive therapy for CIN disease</p> <p>I. Preventive gynecologic surgical intervention for a patient with one or more of the following:</p> <ol style="list-style-type: none"> 1. Hereditary nonpolyposis colorectal cancer (HNPCC) (i.e., Lynch Syndrome) 2. <i>BRCA1</i> or <i>BRCA2</i> positive status when an oophorectomy is performed at the same time 3. Prophylactic ovarian surgery and patient elects to have uterus removed at the same time <p>III. Hysterectomy is considered not medically necessary when the clinical indications are unclear or not adequately documented,</p>	<p>ii. If endometrial stripe on uterine imaging is greater than 4.0mm, endometrial biopsy is required</p> <p>F. Pelvic pain when all of the following criteria are met:</p> <ol style="list-style-type: none"> 1. No other treatable cause for the pain has been established after diligent clinical evaluation (including laparoscopy) and non-gynecological sources of pain (e.g., gastrointestinal, musculoskeletal, psychological, psychosexual, and/or urinary) have been excluded 2. Pain symptoms interfere significantly with activities of daily living (ADLs) at least one or more days each month 3. A conservative treatment (e.g., oral contraceptives, hormone-releasing IUDs, analgesics, non-steroidal medications, gonadotropin-releasing hormone [GnRH] analogs, Depo-Provera, physical therapy), have been unsuccessful or all are contraindicated <p>G. Pelvic relaxation (prolapse) when both of the following criteria are documented:</p> <ol style="list-style-type: none"> 1. Symptomatic uterine prolapse (second-degree or greater; cervix has descended to introitus or further) 2. Failure or contraindication to, or individual non-acceptance of a nonsurgical option, such as the use of a pessary <p>H. Cervical Intraepithelial Neoplasia (CIN) when recurrent high-grade lesion (CIN 2 or CIN 3) is confirmed by biopsy after patient has had prior excisional or destructive therapy for CIN disease</p> <p>I. Preventive gynecologic surgical intervention for a patient with one or more of the following:</p> <ol style="list-style-type: none"> 1. Hereditary nonpolyposis colorectal cancer (HNPCC) (i.e., Lynch Syndrome) 2. <i>BRCA1</i> or <i>BRCA2</i> positive status when an oophorectomy is performed at the same time 3. Prophylactic ovarian surgery and patient elects to have uterus removed at the same time <p>III. Hysterectomy is considered not medically necessary when the clinical indications are unclear or not adequately documented,</p>

POLICY STATEMENT (No changes)	
BEFORE	AFTER
including but not limited to confirmatory examination findings, laboratory results, and imaging studies. IV. The use of robotic surgical techniques is considered not medically necessary when separate payment is requested in addition to hysterectomy.	including but not limited to confirmatory examination findings, laboratory results, and imaging studies. IV. The use of robotic surgical techniques is considered not medically necessary when separate payment is requested in addition to hysterectomy.