

Hysterectomy (for Louisiana Only)

Policy Number: CS196LA.B Effective Date: April 1, 2024

Instructions for Use

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Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

Hysterectomy is proven and medically necessary for management of individuals with BRCA1 or BRCA2 gene mutation or chronic pelvic pain.

Hysterectomy is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual[®] CP: Procedures, Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy.

Click here to view the InterQual[®] criteria.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| CPT Code | Description |
|--------------|---|
| Abdominal | |
| 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) |
| Laparoscopic | |
| 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) |

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| CPT Code | Description |
|----------------|---|
| _aparoscopic | |
| 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) |
| 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) |
| /aginal | |
| 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 |
| 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) |
| 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 |
| _aparoscopic-A | ssisted Vaginal |
| 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) |
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Description of Services

A hysterectomy is a surgical procedure to remove the uterus, and in some cases, the ovaries, and fallopian tubes as well. In a total hysterectomy, the entire uterus, including the cervix, is removed. In a supracervical or partial hysterectomy, the upper part of the uterus is removed, but the cervix is left in place. Benign conditions that might be treated with a hysterectomy include uterine fibroids, endometriosis, pelvic organ prolapse and abnormal uterine bleeding.

Hysterectomies can be performed vaginally, abdominally or with laparoscopic or robotic assistance. In a vaginal hysterectomy (VH), the uterus is removed through the vagina. In an abdominal hysterectomy (AH), the uterus is removed through an incision in the lower abdomen. A laparoscopic approach uses a laparoscope to guide the surgery. A laparoscope is a thin, lighted tube that is inserted into the abdomen through a small incision in or around the navel. The scope has a small camera that projects images onto a monitor. Additional small incisions are made in the abdomen for other surgical instruments used during the surgery. In a total laparoscopic assisted VH, the uterus is removed in small pieces through the incisions or through the vagina. In a laparoscopic-assisted VH, the uterus is removed through the vagina, and the laparoscope is used to guide the surgery. In a robotic-assisted laparoscopic hysterectomy, the surgeon uses a robot attached to the instruments to assist in the surgery.

Clinical Evidence

BRCA1 or BRCA2 Gene Mutation

Gasparri et al. (2022) conducted a systematic review which identified and evaluated the findings of all relevant individual studies on the occurrence of BRCA mutation (BRCAm) in endometrial cancer patients. A systematic literature search was performed in the databases of PubMed, Cochrane, and Web of Science which returned 24 full-text articles that were included for review (13 observational retrospective cohort studies, 3 retrospective case-control studies, 7 observational prospective cohort studies, 1 prospective case-control study, and 1 longitudinal cohort study). The total number of patients analyzed was 37,286 and the mean/median age of patients ranged between 20 and 72 years. A total of 209 BRCAm carriers from 14 studies diagnosed with BRCA1/2m were diagnosed with endometrial cancer. 9 studies calculated the standardized incidence ratio (SIR) for the risk of uterine cancer in BRCAm women. Five authors found a statistical difference in the risk of endometrial cancer for BRCAm patients. The authors concluded there was no strong evidence in favor of performing a routine hysterectomy at the time of risk-reducing salpingo-oophorectomy (RRSO). However, tamoxifen use is associated with a 2–3 fold increase in uterine malignancies and thus a hysterectomy at the time of the RRSO may be an option.

In a systematic review and meta-analysis by Nahshon et al. (2021), the authors studied the possible connection between uterine cancer and patients with BRCA1/2 mutations. A literature search was performed in MEDLINE(R) using the OvidSP interface and PUBMED, Embase, Web of Science and Cochrane Library. After review of 4,591 original articles identified, 8 studies met the inclusion criteria which contained 13,098 patients. After review of the information, the authors found the risk for uterine cancer to be higher in patients with BRCA1/2 mutations, however the addition a prophylactic hysterectomy at the time of a risk reducing bilateral salpingo-oophorectomy (RRBSO) remains controversial. The authors did identify the following benefits for performing a hysterectomy at the time of a RRBSO: 1) Performing a prophylactic hysterectomy can reduce the long-term high risk for uterine cancer; 2) Patients with BRCA1/2 mutations have an increased risk for breast cancer, and as such may potentially need present or future tamoxifen and thus the uterine cancer risk attributed to tamoxifen should be taken into consideration; 3) BRCA1/2 mutated patients who are candidates for hormone replacement therapy may also benefit from hysterectomy; and 4) It has been shown that concurrent hysterectomy at the time of RRBSO may increase the patient's life expectancy by 4.9 additional months.

Portela et al. (2021) conducted a retrospective analysis on patients diagnosed with breast cancer (BC) between 2008 and 2014, who subsequently developed endometrial cancer (EC) within 10 years to those who did not. The authors found a total of 45 BC patients developed EC; of those 24 had T1EC and 21 had T2EC. The relative risk of these patients developing EC was greater than that of the general population. It was also noted that tamoxifen exposure was significantly more prevalent amongst the woman with T2EC and predictive of EC. It was concluded that while the literature indicates patients with BC are at a higher risk for EC, there is insufficient evidence to support prophylactic hysterectomy as a standard practice for these patients. Limitations include small sample size and incomplete medical record documentation.

de Jonge et al. (2021) studied a cohort of BRCA1/2 mutation carriers from the Hereditary Breast and Ovarian cancer study (the Netherlands HEBON study). Two groups were studied which included a total of 5,980 in the BRCA1/2 mutation carrier group and 8,451 in the non-BRCA1/2 mutation carrier group. Two group comparisons were performed: BRCA1/2 mutation carriers vs. Dutch country specific incidence rates and BRCA1/2 mutation carriers vs. non-BRCA1/2 mutation carriers. Overall, the risk of endometrial cancer (EC) in BRCA1/2 mutation carriers was increased 2.83-fold when compared to that of the Dutch EC incidence rates. When the authors reviewed the data from the EC Risk BRCA1/2 mutation carriers and compared them to the non-BRCA1/2 mutation carriers, 58 BRCA1/2 mutation carriers have a two-to threefold increased risk for endometrial cancer. While risk reducing hysterectomy is not routinely recommended, it should be considered and discussed with the patient. Limitations include the possibility of a cancer testing bias and because the BRCA1/2 mutation is not an indication for hysterectomy in the Netherlands the data on previous hysterectomies was unavailable.

Matanes et al. (2020) conducted a meta-analysis to evaluate the risk of endometrial cancer (EC) in BRCA1 or BRCA2 germline mutation carriers and examine the support of a prophylactic hysterectomy at the time of risk-reducing salpingooophorectomy (RRSO). A search was conducted using n PubMed, Cochrane Central Register of Controlled Trials, BIOSIS, Medline (Ovid), Web of Science, ClinicalTrials.gov, and Google Scholar. A total of 11 studies were included; 7 studies were a cohort of individuals from families segregating BRCA1/2 mutations and 4 studies were a single-arm cohort of BRCA1/2 germline mutation carriers who had undergone RRSO. The authors found an occurrence of 0.59% and 0.16% for EC and UPSC in BRCA1/2 mutation carriers, respectively. In addition, it was found that 1 in 161 RCA1 mutation carriers and 1 in 212 BRCA2 mutation carriers were diagnosed with EC during a follow-up period which ranged from 2.4 to 26 years. While the benefits of adding a hysterectomy at the time of RRSO remain controversial, it does appear to prevent some EC, especially in patients that have been treated with tamoxifen, and may also add months onto a patient's survival. A careful risk-benefit assessment is highly recommended, along with patient discussion that includes all the benefits and potential complications. Limitations included the absence of studies with RCTs or comparison group and the results could not be adjusted for tamoxifen use and history of breast cancer, therefore could not be applied to all BRCA carriers.

Kitson et al. (2020) identified 14 cases of endometrial cancer which included data from a cohort of 2,609 women (1,350 BRCA1 and 1,259 BRCA2). Women were eligible for the study if they had a BRCA1 or BRCA2 pathogenic variant identified between 1991 and 2017 and had not undergone a previous hysterectomy. The authors did not find a significant increase in the incidence of endometrial cancer in women with these pathogenic variants, however those exposed to tamoxifen had a significant increase of risk for endometrial cancer in women with the BRCA 1 variant.

Nair et al. (2018) conducted a web-based survey through two online social media groups to target BRCA positive and BRCA interested individuals for this study. 601 respondents completed the survey which included questions that assessed demographics, personal and family histories, decision for type of risk-reducing surgery, and healthcare provided counseling. 487 women in the study had a BRCA mutation, and of these, 339 reported having RRSO, which was consistent with the recommendation for RRSO in BRCA positive patients. Of these 339 respondents, 55.8% of them had a hysterectomy at the time of RRSO. The authors found the most common reason for a patient to have a hysterectomy at the time of a RRSO was provider recommendation; the second most common reason was personal desire. Limitations included the self-reported data, cross-sectional nature, and potential for selection bias.

Chronic Pelvic Pain

Benetti-Pinto et al. (2022) assessed the efficacy of non-surgical treatment for adenomyosis. A literature search was performed in Pubmed, Scopus, and Scielo and the grey literature databases. Primary outcomes included menstrual bleeding through any kind of measurement (such as hemoglobin (Hb) test, number of used pads/day, etc.), pelvic pain measured through the visual analogue scale (VAS); and reduction of uterine volume measured in milliliters or cubic centimeters by TVUS or MRI. Secondary outcome was quality of life measured by questionnaires. A total of 5 studies were included for review and of these, 4 were of RCT design and the other one was prospective, non-randomized. One study was placebo controlled while the others were pharmacological treatment versus surgery or other medications. Comparator groups consisted of levonorgestrel-releasing intrauterine system (LNG-IUS) vs. hysterectomy, LNG-IUS versus combined oral contraceptives; letrozole versus goserelin22; dienogest versus triptorelin24; and dienogest versus placebo. The one study that addressed treatment with LNG-IUS vs hysterectomy, the results showed improvement of quality of life with superior effects on psychological and social life with the LNG-IUS use. The authors found levonorgestrel intrauterine system and dienogest provided positive results for controlling bleeding and pelvic pain when compared to their comparators, however, future RCTs are warranted. Limitations include differences in pain measurement.

Ozdegirmenci et al. (2011) studied 75 women with adenomyosis that was diagnosed on transvaginal ultrasound and magnetic resonance imaging and randomly assigned them to either receive LNG-IUS or hysterectomy (43 to group 1, and 32 to group 2). Clinical measurements of menstrual bleeding were obtained by the number of used pads/day during menstruation and hemoglobin (Hb) levels. The quality of life (QOL) was measured by the World Health Organization Quality of Life-Short Form, Turkish Version (WHOQOL-BREF TR) which contained 26 questions covering four domains: physical health, psychological health, social relationships, and environment. The questionnaire was completed prior to surgery and again one year later. In the LNG-IUS group, 54.1% of the patients were amenorrheic at the end of the first year. While both treatments appear to show improvements in health-related QOL, the authors found LNG-IUS seemed to have superior effects on psychological and social life which may be a promising alternative therapy to that of a hysterectomy. Limitations include lack of evaluating the ferritin levels and the effect of LNG-IUS on the size of adenomyotic lesions.

Heliövaara-Peippo et al. (2009) conducted a randomized controlled trial to evaluate the changes in lower abdominal pain and back pain among women with menorrhagia treated by hysterectomy or LNG-IUS. 117 participants were assigned to the hysterectomy group and 119 participants were assigned to the LNG-IUS group. Questionnaires containing questions about BMI, medication usage, parity and education were filled out at baseline and again on any follow-up visits. The Likertscale was used for questions on frequency of lower abdominal pain and back pain during the last six months. The scores ranged from 1 to 4 (1 indicating never or rarely, 2 indicating monthly, 3 indicating weekly and 4 indicating nearly every day). The visual analogue scale was used to rate the intensity of pain during the last six months (1 indicating no pain and 7 indicating the worst possible pain). Follow-up visits took place at 6 months, 12 months and 5 years post hysterectomy or insertion of LNG-IUS. At six months, women in both groups had less frequent back pain when compared to baseline; the hysterectomy group had a reduction in lower abdominal pain when compared to the LNG IUS group, but the difference was not significant. No significant differences were seen in the pain scores. At 12 months, women in the

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LNG-IUS group had additional lower abdominal pain than women in the hysterectomy group. Between 12 months and 5 years the lower abdominal pain score decreased in the LNGIUS group, but not in the hysterectomy group. By five years, women in both groups had less lower abdominal pain when compared to the baseline results, however, back pain increased in the hysterectomy group. The authors concluded that both hysterectomy and LNG-IUS decrease back pain and lower abdominal pain overall for women aged 35-49 years.

Clinical Practice Guidelines American College of Obstetricians and Gynecologists (ACOG)

In ACOG bulletin #793, Hereditary Cancer Syndromes and Risk Assessment, the committee opinion addresses updates related to hereditary breast and ovarian cancer, cascade testing, and referrals to genetics specialists. It is silent for patients and the need for prophylactic hysterectomy.

In an ACOG Committee Opinion #601, Tamoxifen and Uterine Cancer (2018) the following recommendations are made:

- Women taking tamoxifen should be informed about the risks of endometrial proliferation, endometrial hyperplasia, endometrial cancer, and uterine sarcomas.
- Postmenopausal women taking tamoxifen should be closely monitored for symptoms of endometrial hyperplasia or cancer.
- If atypical endometrial hyperplasia develops, appropriate gynecologic management should be instituted, and the use of tamoxifen should be reassessed. If continued use of tamoxifen therapy is advised and the risks are accepted by the patient, hysterectomy should be considered in women with atypical endometrial hyperplasia. Tamoxifen use may be restituted following hysterectomy for endometrial carcinoma in consultation with the physician responsible for the woman's breast care.

National Comprehensive Cancer Network (NCCN) Clinical Guidelines

The National Comprehensive Cancer Network (NCCN) clinical guidelines for breast, ovarian, and pancreatic oncology state patients should discuss the risks and benefits of concurrent hysterectomy at the time of risk-reducing salpingo-oophorectomy (RRSO) for individuals with a BRCA1 P/LP variant. In addition, the panel recommends "RRSO for carriers of a known BRCA1/2 P/LP variant, typically between 35 and 40 years of age for carriers of a BRCA1 P/LP variant. Since ovarian cancer onset tends to be later in carriers of a BRCA2 P/LP variant, it is reasonable to delay RRSO for management of ovarian cancer risk until between 40 and 45 years of age, unless age at diagnosis in the family warrants earlier age for consideration of this prophylactic surgery.

National Institute for Health and Care Excellence (NICE)

The laparoscopic hysterectomy for endometrial cancer guideline (IPG356) indicates current evidence on the safety and efficacy of laparoscopic hysterectomy (including laparoscopic total hysterectomy and laparoscopically assisted vaginal hysterectomy) for endometrial cancer is adequate to support the use of this procedure. However, it is silent on the position of prophylactic hysterectomy for BRCA mutation.

In a 2017 diagnosis and management guideline for endometriosis, NICE identifies chronic pelvic pain (pelvic pain lasting for 6 months or longer) as a sign/symptom of endometriosis.

Society of Obstetricians and Gynaecologists of Canada (SOGC)

The inclusion of hysterectomy with risk-reducing salpingo-oophorectomy for BRCA variant carriers should be individualized, taking into account risk factors for uterine cancer, other uterine pathology, and tamoxifen use (strong, moderate).

There are insufficient data to routinely recommend hysterectomy to reduce the risk of papillary serous uterine cancer in BRCA1 mutation carriers (conditional, low). (Jacobson et al., 2018).

In chapter 5 of the Consensus Guidelines for the Management of Chronic Pelvic Pain (No. 164), the following recommendations are made:

- Hysterectomy for endometriosis or adenomyosis with ovarian conservation can be an acceptable alternative.
- Hysterectomy can be indicated in the presence of severe symptoms with failure of other treatment when fertility is no longer desired.

(Jarrell et al., 2018)

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The interventions described in this policy are surgical procedures and are not subject to FDA approval. There are many surgical instruments approved for use in pelvic and abdominal surgery. Refer to the following website to search for specific products. Available at: <u>http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm</u>. (Accessed September 8, 2023)

A laparoscopic power morcellator is a <u>Class II</u> medical device used during laparoscopic surgery and commonly used in hysterectomy procedures. Product labeling for laparoscopic power morcellators recommends that manufacturers of laparoscopic power morcellators with a general indication or a specific gynecologic indication prominently include the following black box warning and contraindications in their product labeling:

- Warning:
 - 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.
- Contraindications:
 - Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.
 - 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 via a mini-laparotomy incision.

Refer to the following websites for additional information:

- https://www.fda.gov/medical-devices/surgery-devices/laparoscopic-power-morcellators
- https://www.fda.gov/media/90012/download
- <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-labeling-laparoscopic-power-morcellators</u>

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Policy History/Revision Information

| | Date | Summary of Changes |
|-----|----------|--|
| 12/ | /01/2024 | Template Update |
| | | Modified font and InterQual[®] reference link styles; no change to policy content |
| 04/ | /01/2024 | Supporting Information |
| | | • Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information |
| | | Archived previous policy version CS196LA.A |

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual[®] criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.