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DYNAMIC SPECTRAL IMAGING SMART COLPOSCOPY (DYSIS)

Policy # 675

Implementation Date: 10/04/23

Review Dates: 10/17/24

Revision Dates:

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Computer-aided colposcopy with cervical mapping is an innovative technology that creates the data to help healthcare professionals detect cervical lesions efficiently. Using a DYSIS Colposcope, healthcare professionals perform a standard colposcopic examination while the DYSIS proprietary software quantifies acetowhitening changes objectively, to then display the color-coded DYSIS map.

DYSIS with Pseudo-Color Imaging (PCI) is a digital colposcope designed to image the cervix and lower genital tract under illumination and magnification. Colposcopy is indicated for women with an abnormal Pap smear to affirm normality or detect abnormal appearances consistent with neoplasia, often with directed biopsy. The PCI feature is an adjunctive tool for displaying areas of acetowhitening. It is a tool that should not be used as a substitute for a thorough colposcopic evaluation.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does not cover dynamic spectral imaging smart colposcopy (DYSIS) due to the lack of specificity this technology offers in colposcopic evaluations; this meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Dynamic Spectral Imaging Smart Colposcopy (DYSIS), continued

Billing/Coding Information

Not covered: the following codes are considered experimental/investigational

CPT CODES

57465 Computer-aided mapping of cervix uteri during colposcopy, including optical dynamic spectral imaging and algorithmic quantification of the acetowhitening effect (list separately in addition to code for primary procedure)

Key References

1. Hayes, Inc. Clinical Evidence Ad Hoc Research. DYSIS-Dynamic Spectral Imaging Smart Colposcopy. September 26, 2023.

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MEDICAL POLICY

ENDOMETRIAL ABLATION

Policy # 329

Implementation Date: 12/12/06

Review Dates: 12/20/07, 10/13/11, 6/20/13, 4/17/14, 5/7/15, 4/14/16, 4/27/17, 9/18/18, 4/8/19, 8/8/19, 8/20/20, 8/19/21, 7/14/22, 8/18/23, 8/29/24

Revision Dates: 12/18/08, 12/17/09, 10/21/10, 5/1/12

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Menstrual disorders and abnormal uterine bleeding (AUB), including heavy menstrual bleeding (HMB), are among the most frequent gynecologic complaints. AUB refers to bleeding that is excessive or occurs outside of normal cyclic menstruation. AUB is described by a variety of terms and may be caused by several genital and non-genital tract conditions, systemic disorders, and medications. AUB can result in anemia, interfere with daily activities, and raise concerns about uterine cancer. Most women with heavy or prolonged uterine bleeding require medical attention but can be managed on a non-acute, outpatient basis. Occasionally, uterine bleeding is severe enough to necessitate immediate medical evaluation and treatment.

Women with abnormal uterine bleeding have a variety of therapeutic options. Endometrial ablation has become an increasingly popular treatment since it is minimally invasive and successful ablation avoids chronic use of medications. Various techniques are employed when performing endometrial ablation; some use ultrasound guidance. Others use a hysteroscopic approach in which the lining of the uterus is directly visualized using a hysteroscope. Endometrial ablation may be performed in the office setting, outpatient surgical center, or hospital, depending upon patient characteristics and physician preference.

The ablation portion of these procedures may use heat or cold. When heat is employed, it may be generated from different sources. These sources may be hot water (hydrothermal ablation), microwave ablation, or radiowaves.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health covers endometrial ablation using cryoablative, electrical, radiofrequency, or hydroablative techniques, as these therapeutic techniques have equally proven efficacy and safety in the treatment of abnormal uterine bleeding.

Select Health does NOT cover endometrial ablation using microwave or laser techniques, as these therapeutic techniques have failed to demonstrate equal efficacy or safety to other currently available techniques and are thus felt to be unproven, especially given the availability of multiple other techniques to treat abnormal uterine bleeding. This meets the plan's definition of experimental/investigational.

Endometrial Ablation, continued

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or the [manual website](#)

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

The literature identified for this review suggests that global techniques are performed more quickly with fewer complications and less anesthesia and with less technical skill required. However, the risk for serious complications, especially uterine perforation, is still present with each technique.

In terms of efficacy, the literature offers mixed evidence for the relative efficacy of the different global ablative techniques. Much of the literature consists of observational retrospective studies where patient selection and treatment were not systematically controlled. Comparisons across studies are further complicated by varying definitions of treatment success, blood loss, patient satisfaction, and heterogeneous patient samples and treatment protocols. Most randomized controlled studies compared global techniques with standard ablation, typically, electrocautery with rollerball.

A few studies have directly compared clinical outcomes from two or more global ablative techniques. Abbott et al. randomly assigned 57 women with menorrhagia to undergo NovaSure or balloon ablation with Cavaterm (European balloon device). While NovaSure produced a higher rate of amenorrhea at 12 months (11% vs. 43%), both procedures were equally effective overall (89% of balloon patients achieved eumenorrhea or better vs. 86% with NovaSure). A similar study by Bongers et al. measured health-related quality of life in women randomly assigned to undergo NovaSure or balloon ablation. Again, higher rates of amenorrhea were found in NovaSure patients, but there was no difference in quality of life between the two groups.

Hawe et al. compared ablation outcomes from the Cavaterm balloon with those from laser ablation in 72 women randomized to either procedure. At 1 year, rates for amenorrhea and hypomenorrhea were not significantly different across groups nor were patient satisfaction or perceived health. In Laberge et al., NovaSure produced less intraoperative and postoperative pain relative to ThermoChoice (balloon) ablation in 67 premenopausal women randomly assigned to either treatment.

Table 1 summarizes clinical outcomes published since 2003 for different endometrial ablation techniques. As the table demonstrates, success and failure rates, subsequent hysterectomy or re-ablation, and patient satisfaction are fairly similar across techniques and no single technique can be identified as the “most effective.” No therapy has enough long-term data to reliably estimate re-ablation or hysterectomy rates, or risk for cancer in treated patients. There are no studies comparing in-office treatment to hospital-based ablation so no conclusions can be drawn about the relative benefits/risks of treatment in either setting.

Table 1. Clinical outcomes published since 2003 for different endometrial ablation techniques

| | Resection | Rollerball | Cryotherapy | Hydrothermal | Microwave | Bipolar Desiccation | Heated fluid (balloon) | Laser |
|---|-----------|------------|-------------|--------------|-----------|---------------------|------------------------|-------|
| Satisfaction (satisfied or very satisfied) 1 yr | 53-94% | 82-100% | 86% | | 75-99% | 92-95% | 62-100% | |
| Satisfaction (satisfied or very satisfied) 2 yr | 31-67% | 75-98% | 67-91% | | 68-79% | | 39-96% | 94.5 |
| Satisfaction (satisfied or very satisfied) 3 yr | 91% | 71-97% | | 98% | | | 78% | 93 |
| Satisfaction (satisfied or very satisfied) 5 yr | 74% | 44% | | | 86% | | 42% | |

Endometrial Ablation, continued

| | Resection | Rollerball | Cryotherapy | Hydrothermal | Microwave | Bipolar Desiccation | Heated fluid (balloon) | Laser |
|----------------------------------|-----------|------------|-------------|--------------|-----------|---------------------|------------------------|--------|
| % Success (1 yr) | 2-90% | 75-92% | 67-77% | 68-94% | 76-92% | 69-97% | 83-100% | 69-98% |
| % Success (2 yr) | | 76-92% | 94% | 92% | 70% | 89% | 83-89% | |
| % Success (3 yr) | | 91-94% | | 94% | 85% | 96% | 74-93% | |
| % Success (5 yr) | | 97% | | | | | 77-95% | |
| % Amenorrhea (1yr) | 25-46% | 27-56% | 22-28% | 35-53% | 10-61% | 36-59% | 3-68% | 39-71% |
| % Amenorrhea (2yr) | | 41-46% | | 46% | 47% | 28% | 5-46% | |
| % Amenorrhea (3yr) | 24% | 46% | | 53% | 38% | 65% | | 59% |
| % Amenorrhea (4yr) | | | | | | | 47-58% | |
| PBAC 1 yr | | 24-75 | | | 10 | 3 | 21-60 | |
| % Continued menorrhagia (1 yr) | 7% | 15 | | 9-18% | | 4-9% | 0-23% | 2-4% |
| % Continued menorrhagia (2 yr) | | 8% | | 8% | | | 10-57% | |
| % Continued menorrhagia (3-5 yr) | 9% | 9% | | 6% | 15% | 3% | 9% | 5% |
| % Reablation (1 yr) | | 1% | | | | 2-6% | 0-37% | 15% |
| % Reablation (2 yr) | | 2-8% | 1.2% | | | 9% | 1-10% | |
| % Reablation (3 yr) | | 4% | | 2% | | 0.9% | 1% | |
| % Reablation (5 yr) | | 2-11% | | | | | 2-12% | |
| % F/u hysterectomy (1 yr) | 2-15% | 6.8% | | 9% | | 1-3% | 0-11 | 5% |
| % F/u hysterectomy (2 yr) | 2-13% | 7-20% | 7% | | 12-21% | 13% | 2-12% | |
| % F/u hysterectomy (3 yr) | | 6-7% | | 9% | | 2.8% | 11% | |
| % F/u hysterectomy (4 yr) | | | | | | | 8% | |
| % F/u hysterectomy (5 yr) | 25% | 17-34% | | | 16% | | 13-34% | |
| Uterine perforation | 0% | 5% | | | | | 0% | 0% |
| General anesthesia | 9.2% | 76% | | | 37% | | 0% | 9% |
| IV sedation | | 18% | | | 62% | | 0% | |
| Local+IV | | | 54% | 45% | | 73% | 39% | |
| Laceration of cervix | | 5% | | | | | 0 | |
| Electrolyte imbalance | | 2% | | | | | 0% | |
| Suspected perforation | | 2% | | | | | 0% | |
| Pain | | 2% | | | | | 0 | |
| Nausea | | 2% | 2% | 22% | | 2-10% | 24-33% | |
| Cramping/pelvic pain | | | 23% | 32% | | 3% | 92% | |

In a recent review by Sharp, the author noted that subjective satisfaction rates are uniformly high, regardless of method, despite wide variability in reported rates of amenorrhea in the literature. He further noted that the rate of complications is low when these techniques are used in the hands of well-trained physicians working under protocols compared to some of the major complications observed with a wide range of physicians. When used correctly, these devices are relatively safe.

Clinical factors, patient preferences, and reimbursement may also influence which treatment method is employed. For example, a patient with an irregularly shaped uterus may be treated with hydrothermal ablation to ensure that all the endometrial lining is treated, while a patient who desires minimal anesthesia may prefer cryoablation. A patient with uterine fibroids may elect to undergo microwave therapy, which is the only ablative treatment approved by the FDA for this indication. Of course, providers may choose to perform those procedures that offer the best reimbursement rates from third party payers. Until more conclusive evidence is published demonstrating the superiority of one technique over another, these factors will likely play an equally important role in determining which global ablation therapy is employed.

A literature review performed in October 2010 identified an article by Pennix et al. The objective was to compare the effectiveness of two second-generation ablation techniques, bipolar radiofrequency impedance-controlled endometrial ablation and hydrothermablation, in the treatment of menorrhagia. They included 160 women in the study, of which 82 were allocated to the bipolar group and 78 to the hydrotherm group. No complications occurred in either of the treatment groups. After 12 months, 87% (65 of 75) of the patients in the bipolar group were completely satisfied with the result of the treatment, compared with 68% (48 of 71) in the hydrotherm group (relative risk 1.3, 95% confidence interval [CI] 1.03–1.6). The amenorrhea rates were 47% (35 of 75) in the bipolar group and 24% (17 of 71) in the hydrotherm group (relative risk 2.0, 95% CI 1.2–3.1). The relative risks for a reintervention in the bipolar

Endometrial Ablation, continued

group, compared with the hydrotherm group, was 0.29 (95% CI 0.12–0.67), whereas, for hysterectomy, this was 0.49 (95% CI 0.15–1.5). They concluded, in the treatment of menorrhagia, bipolar radiofrequency endometrial ablation system is superior to hydrothermal ablation.

A Medical Technology Assessment performed in April 2012 focusing on endometrial cryoablation identified only two systematic reviews, and only one study from the primary literature was identified, since the last review in 2006. The National Institute for Health and Clinical Excellence (NICE) published shortly after the last Medical Technology Assessment in 2006, noted though limited short-term evidence on the safety and efficacy of cryotherapy currently exists, that the procedure may be appropriate in “carefully selected patients.” No detail is given as to who these carefully selected patients are. The 2009 Cochrane review stated it may be useful in: “... women with a complaint of heavy menstrual bleeding without uterine pathology.” The Cochrane review concluded that endometrial cryoablation did not offer any improvement over older hysteroscopic treatments for menorrhagia (laser, transcervical resection of the endometrium and roller ball) as these older techniques have similar risk and reward profiles with newer techniques such as cryoablation.

Duleba et al. segmented 279 patients into two groups, cryoablation (n = 193) or rollerball (n = 86), where the cryoablation group reported 20% worse bleeding than did the roller ball cohort. Of the three primary endpoints (anesthesia need, success rates and decrease in bleeding) the only metric in which cryoablation outperformed roller ball therapy was in the amount of anesthesia needed to perform the procedure.

Limited evidence points to cryoablation as being a safe and effective method for treating menorrhagia. Given the lack of published comparative trials, looking at similar populations of patients with menorrhagia using different devices, it is not possible to draw conclusions as to whether one method has superior outcomes to other methods. However, the current evidence, though limited, demonstrates endometrial cryoablation to be a safe and effective technique in the treatment of menorrhagia equal to alternative therapies.

Billing/Coding Information

CPT CODES

Covered: For the indications listed above

| | |
|--------------|---|
| 58353 | Endometrial ablation, thermal without hysteroscopic guidance |
| 58356 | Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed |
| 58563 | Hysteroscopy, surgical; with endometrial ablation (e.g., endometrial resection, electrosurgical ablation, thermoablation) |

Not Covered: Investigational/Experimental/Unproven for this indication

| | |
|--------------|--|
| 0071T | Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue |
| 0072T | ; total leiomyomata volume greater or equal to 200 cc of tissue |

HCPCS CODES

No specific codes identified

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MEDICAL POLICY

HYSTERECTOMY/OOPHORECTOMY

Policy # 620

Implementation Date: 1/1/18

Review Dates: 2/20/19, 12/18/19, 12/17/20, 11/30/21, 1/13/23, 12/21/23, 2/5/25

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Related Medical Policies:

[#448 Prophylactic Oophorectomy/Salpingo Oophorectomy](#)[#386 Gender Affirming Medical and Surgical Treatment](#)**Disclaimer:**

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

A hysterectomy is a surgical procedure to remove the uterus, and in some cases, the ovaries and fallopian tubes as well.

An abdominal hysterectomy is a surgical procedure that removes the uterus through an incision in the lower abdomen. The uterus, or the womb, is where a baby grows when a woman is pregnant. A partial hysterectomy removes just the uterus, leaving the cervix intact. A total hysterectomy removes the uterus and the cervix.

Sometimes a hysterectomy includes removal of one or both ovaries and fallopian tubes, a procedure called a total hysterectomy with salpingo-oophorectomy.

A hysterectomy can also be performed through an incision in the vagina (vaginal hysterectomy) or by a laparoscopic or robotic surgical approach, which uses long, thin instruments passed through small abdominal incisions.

Oophorectomy is the surgical removal of one or both ovaries. It can be unilateral (removal of one ovary) or bilateral (removal of both ovaries). Oophorectomy is performed for various reasons, including treatment of conditions like ovarian cancer, breast cancer, endometriosis, and ovarian cysts, as well as for preventive measures in individuals at higher risk of developing ovarian or breast cancer.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

I. Select Health considers hysterectomy as medically necessary when any one of the following criteria are met:

- A. Cancer, precancerous, high cancer risk due to one of the following:
 - i. Endometrial intraepithelial neoplasia (EIN) (previously called atypia)
 - ii. Benign hyperplasia (simple or complex hyperplasia without atypia), and persists despite maximum medical therapy
 - iii. Persistent CIN (cervical intraepithelial neoplasia) CIN 1, CIN 2, or CIN 3, or cervical cancer by pathology by endocervical curettage or biopsy, findings continued > 6 months post-excisional procedure

Hysterectomy/Oophorectomy, continued

- iv. Endocervical adenocarcinoma in situ by biopsy
- v. Endometrial cancer by pathology
- vi. Ovarian cancer by imaging
- vii. Tubal cancer by imaging
- viii. Lynch syndrome mutation
- ix. BRCA1 or BRCA2 gene mutation
- x. RAD51C/RAD51D (hysterectomy is allowed when performed in conjunction with oophorectomy)
- xi. Gestational trophoblastic disease
- xii. Uterine sarcoma

B. Abnormal Uterine Bleeding (AUB): Defined as one of the following: > 7 days per cycle, or > loss of 80 cc per cycle, or abnormal frequency: periods that start at intervals < 24 days, or abnormal infrequency: periods that start at intervals > 38 days.

1. Pre-Menopausal AUB

Hysterectomy is allowed if all the following are met:

- a) Hormonal therapy for at least 12 weeks, would include one the following treatment options: cyclic or continuous combined oral contraceptive or progestin only hormone therapy (including oral, dermal patch, or vaginal ring), Danazol, GnRH agonists, LNG-IUS (Levonorgestrel-containing Intrauterine system), tranexamic acid, except if:
 - i. They are contraindicated; or
 - ii. They are not tolerated; or
 - iii. Symptoms are ongoing despite treatment; or
 - iv. They are not appropriate for severity of patient's condition (e.g., severe persistent bleeding, acute anemia, postmenopausal age) or clinical scenario

AND

- b) Conservative surgery (e.g., endometrial ablation, endometrial polypectomy, D&C) cannot be used because of one or more of the following:
 - i. Procedure is contraindicated (extreme uterine flexion or version, extremely thin myometrium); or
 - ii. Procedure was tried but did not adequately treat patient's condition; or
 - iii. Procedure is not appropriate for severity of patient's condition or clinical scenario;

AND

- c) If ultrasound is abnormal or if member is greater than 44 years of age then endometrial biopsy or hysteroscopy is required.

2. Post-Menopausal AUB, with all the following:

- a) Normal vaginal and cervical exam; and
- b) Endometrial biopsy has been completed; and
- c) No improvement with stopping or changing hormones for at least 3 months; documentation must clarify the need for hormonal therapy if continued.

C. Postpartum uterine bleeding less than 48 hours with life-threatening condition.

D. Postpartum uterine bleeding ≥ 48 hours post-delivery, with all the following:

- i) Retained POC (vaginal, vulvar, or cervical laceration excluded); and
- ii) Failure of treatments as indicated, including but not limited to, vigorous uterine massage, or manual extraction of placenta, or D&C, or balloon tamponade; and

Hysterectomy/Oophorectomy, continued

- iii) Failure of 2 of the following medications:
 - Pitocin (Oxytocin)
 - Methergine (Methylergonovine)
 - Prostaglandin
 - Hemabate (Carboprost)
 - Tranexamic acid
- E. Adenomyosis by clinical history and exam, with failure of NSAIDS > 12 weeks (if tolerated), and any one of the following:
 - i. Hormone therapy > 12 weeks; or
 - ii. LNG-IUS (Levonorgestrel-containing Intrauterine system) > 12 weeks; or
 - iii. Tranexamic acid > 12 weeks; or
 - iv. GnRH agonist > 12 weeks; or
 - v. Uterine artery embolization.
- F. Pelvic Pain/Dyspareunia/Dysmenorrhea (must have all the following)
 - i. Pain persists despite NSAIDS > 12 weeks (unless contraindicated); and
 - ii. Pelvic pain, abdominal pain or dyspareunia with GI, GU, musculoskeletal, or other defined gynecologic cause excluded; and
 - iii. Psychiatric disorder excluded by screening or currently well-managed; and
 - iv. Imaging or diagnostic laparoscopy within 2 years is otherwise non-diagnostic; and
 - v. Persistence after hormone therapy > 12 weeks or LNG-IUS or GnRH agonist > 12 weeks or antibiotic treatment x 2 courses (chronic abdominal/ PID (Pelvic Inflammatory Disease) or other infectious etiology) or uterine artery embolization.
- G. Uterine leiomyomas (fibroids) (must meet both i and ii):
 - i. Uterine leiomyomas not amenable to hysteroscopic treatment; and
 - ii. At least one of the following (a-d):
 - a. Abnormal bleeding associated with leiomyomas; or
 - b. Uterine size doubled by US in 1 year; or
 - c. Hydroureter, ureteral, bladder, or rectal compression resulting in urinary frequency/urgency/retention or rectal urgency/retention due to mass compression from fibroids; or
 - d. Pelvic pain, abdominal pain or dyspareunia with GI, GU, musculoskeletal, or other defined gynecologic cause excluded
- H. Endometriosis by laparoscopy with uterine involvement, and has failed any of the following therapies for > 12 weeks within the last 5 years:
 - i. GnRH (Gonadotropin-releasing hormone) agonist; or
 - ii. GnRH antagonist; or
 - iii. Danocrine (Danazol); or
 - iv. LNG-IUS (Levonorgestrel-containing Intrauterine system); or
 - v. Hormone therapy.
- I. Uterine Prolapse (must meet either a or b; and must also meet c and d):
 - a. Symptomatic pelvic organ prolapse*, with an apical descent of 50% total vaginal length (TVL) or greater;

OR

 - b. Symptomatic pelvic organ prolapse*, where the anterior vaginal wall (cystocele) is classified as stage III prolapse (+2 or greater), with a genital hiatus of 4cm or greater under Valsalva;

Hysterectomy/Oophorectomy, continued

AND

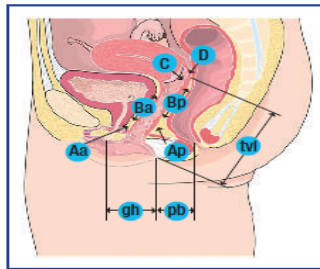
- c. Discussion of conservative treatment options, including but not limited to, pessary and pelvic floor PT.

AND

- d. The surgical plan includes procedures, e.g., colpopexy, to support the vaginal apex.

*Symptomatic pelvic organ prolapse refers to the following patient symptoms: A sensation of pressure, bulge, fullness, heaviness, things falling out, tissue protruding from the vagina, splinting to void, incomplete bladder emptying. (see chart below for additional information)

POP-Q Exam – Reference Guide



The pelvic organ prolapse quantification (POP-Q) exam is used to quantify, describe, and stage pelvic support.

- There are 6 points measured at the vagina with respect to the hymen.
- Points above the hymen are negative numbers; points below the hymen are positive numbers.
- All measurements except tvl are measured at maximumValsalva.

| Point | Description | Range of Values |
|---|--|-----------------|
| Aa | Anterior vaginal wall 3 cm proximal to the hymen | -3 cm to +3 cm |
| Ba | Most distal position of the remaining upper anterior vaginal wall | -3 cm to +tvl |
| C | Most distal edge of cervix or vaginal cuff scar | |
| D | Posterior fornix (N/A if post-hysterectomy) | |
| Ap | Posterior vaginal wall 3 cm proximal to the hymen | -3 cm to +3 cm |
| Bp | Most distal position of the remaining upper posterior vaginal wall | -3 cm to + tvl |
| Genital hiatus (gh) – Measured from middle of external urethral meatus to posterior midline hymen | | |
| Perineal body (pb) – Measured from posterior margin of gh to middle of anal opening | | |
| Total vaginal length (tvl) – Depth of vagina when point D or C is reduced to normal position | | |

POP-Q Staging Criteria

| | |
|-----------|--|
| Stage 0 | Aa, Ap, Ba, Bp = -3 cm and C or D ≤ - (tvl - 2) cm |
| Stage I | Stage 0 criteria not met and leading edge < -1 cm |
| Stage II | Leading edge ≥ -1 cm but ≤ +1 cm |
| Stage III | Leading edge > +1 cm but < + (tvl - 2) cm |
| Stage IV | Leading edge ≥ + (tvl - 2) cm |

REFERENCE: Bump RC, Mattiasson A, Bo K, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *Am J Obstet Gynecol.* 1996;175:13.

J. Infection (must meet either a or b):

- a. Chronic pelvic inflammatory disease, including:
- i. Pelvic pain; and
 - ii. Acute pelvic inflammatory disease ≥ 2 episodes or requiring persistent antibiotic; and
 - iii. Infection documented in ≥ 1 episode by culture.

OR

Hysterectomy/Oophorectomy, continued

b. Tubo-ovarian abscess by imaging, with:

- i. Ectopic excluded; and
- ii. Pelvic pain, or abdominal tenderness, or persistent adnexal mass, or temperature > 100.4, or WBC > normal; and
- iii. Symptoms worsening during IV antibiotic or persistent antibiotic required.

K. Removal of Essure Device

Select Health covers removal of Essure device if the member has any of the following symptoms related to the device:

- i. Abdominal/pelvic pain
- ii. Heavy/irregular menses not related to other pathologies
- iii. Device migration
- iv. Nickel allergy/hypersensitivity

Except as described in medical policy #386: Gender Affirming Medical and Surgical Treatment, Select Health does NOT cover hysterectomy for any other indication as it is considered not medically necessary.

II. Oophorectomy Criteria

A. Select Health covers oophorectomy with hysterectomy when any of the following criteria are met:

- i. Endometrial cancer is present, or
- ii. Ovarian pathology is present, or
- iii. Patient is ≥ age 51 years with an average risk of ovarian cancer, or
- iv. Patient is at increased risk for ovarian cancer due to one of the following:
 - a. Genetic mutation confirmed by molecular testing for breast and ovarian cancer susceptibility genes (ATM, BRCA1, BRCA2, BRIP1, Lynch syndrome genes [MLH1, MSH2, MSH6, EPCAM, PMS2], PALB2, RAD51C, and RAD51D)
 - b. Personal history of breast cancer and one first-degree* relative with a history of ovarian cancer
 - c. Two or more first-degree* relatives with early onset ovarian and/or breast cancer
 - d. Patient has 1 first-degree relative (e.g., mother, sister, daughter), and 1 or more second-degree** relatives (maternal or paternal aunt or grandmother) with ovarian cancer
 - e. Known familial cancer syndrome associated with increased risk of ovarian cancer, which would include breast cancer and hereditary nonpolyposis colon cancer (HNPCC) (includes Lynch syndrome); after completion of childbearing
 - f. Infertility
 - g. Polycystic ovarian syndrome
 - h. Endometriosis
 - i. Age ≥ 45 years with current smoking history, or
- v. Breast cancer treatment
 - a. Premenopausal woman with estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+) breast cancer

III. Salpingectomy Criteria

Select Health covers salpingectomy with hysterectomy for patients at any age.

** A first-degree relative is defined as a blood relative with whom an individual shares approximately 50% of his/her genes, including the individual's parents, full siblings, and children.*

Hysterectomy/Oophorectomy, continued

**** A second-degree relative is defined as a blood relative with whom an individual shares approximately 25% of his/her genes, including the individual's grandparents, grandchildren, aunts, uncles, nephews, nieces, and half-siblings.**

*****Staging of Pelvic Organ Prolapse**

| Baden-Walker System | | Pelvic Organ Prolapse Quantification System | |
|---------------------|---|---|--|
| Grade | Description | Stage | Description |
| 0 | Normal position for each respective site, no prolapse | 0 | No prolapse |
| 1 | Descent halfway to the hymen | I | Greater than 1 cm above the hymen |
| 2 | Descent to the hymen | II | 1 cm or less proximal or distal to the plane of the hymen |
| 3 | Descent halfway past the hymen | III | Greater than 1 cm below the plane of the hymen, but protruding no farther than 2 cm less than the total vaginal length |
| 4 | Maximal possible descent for each site | IV | Eversion of the lower genital tract is complete |

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

Studies have shown that a vaginal approach to hysterectomy has fewer complications, requires a shorter hospital stay and is associated with better outcomes than a laparoscopic or abdominal approach.

A Cochrane review (Aarts et al., 2015) of 47 randomized controlled trials (n = 5102) evaluating the abdominal, laparoscopic, and vaginal approach concluded that vaginal hysterectomy (VH) appears to be superior to laparoscopic and abdominal hysterectomy. VH is preferred to abdominal hysterectomy (AH) when possible, citing the advantages of a more rapid recovery and fewer postoperative complications of fever and/or infection. Where VH is not possible, a laparoscopic approach is preferred over AH with the

Hysterectomy/Oophorectomy, continued

same advantages as the vaginal approach but requires a longer operating time and had more urinary tract injuries.

Another Cochrane review (Nieboer et al., 2009) of 34 randomized controlled trials (n = 4495) of AH, total laparoscopic hysterectomy (TLH), and VH concluded that VH should be performed in preference to AH where possible. The authors found that VH meant a quicker return to normal activities, fewer infections and episodes of raised temperature after surgery and a shorter hospital stay compared to AH. When a vaginal approach is not possible, a laparoscopic approach may avoid the need for an AH. TLH meant a quicker return to normal activities, less blood loss and a smaller drop in blood count, a shorter hospital stay and fewer wound infections and episodes of raised temperature after surgery compared to AH; however, laparoscopic surgery is associated with longer operating times and higher rates of urinary tract injury. More research is needed, particularly to examine the long-term effects of the different types of surgery.

An ACOG (American Congress of Obstetricians and Gynecologists) committee opinion states that vaginal hysterectomy is the approach of choice whenever feasible. Evidence demonstrates that, in general, vaginal hysterectomy is associated with better outcomes and fewer complications than laparoscopic or abdominal hysterectomy. Laparoscopic hysterectomy is an alternative to abdominal hysterectomy when a vaginal hysterectomy is not indicated or feasible.

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. A November 24, 2014 FDA Safety Communication recommends that manufacturers of laparoscopic power morcellators with a general indication or a specific gynecologic indication prominently include the following black box 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 in their product labeling should read "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.

Billing/Coding Information

CPT CODES

| | |
|--------------|---|
| 45560 | Repair of rectocele (separate procedure) |
| 57250 | Posterior colporrhaphy, repair of rectocele with or without perineorrhaphy |
| 57260 | Combined anteroposterior colporrhaphy; |
| 57265 | Combined anteroposterior colporrhaphy; with enterocele repair |
| 57280 | Colpopexy, abdominal approach |
| 57282 | Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus) |
| 57283 | Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy) |
| 57425 | Laparoscopy, surgical, colpopexy |
| 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 (eg, Marshall-Marchetti-Krantz, Burch) |
| 58180 | Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s) |
| 51925 | Closure of vesicouterine fistula; with hysterectomy |

Hysterectomy/Oophorectomy, continued

| | |
|--------------|---|
| 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) |
| 58260 | Vaginal hysterectomy, for uterus 250 g or less; |
| 58262 | ; with removal of tube(s), and/or ovary(s) |
| 58263 | ; 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 | ; with repair of enterocele |
| 58275 | Vaginal hysterectomy, with total or partial vaginectomy |
| 58280 | Vaginal hysterectomy, with total or partial vaginectomy; with repair of enterocele |
| 58290 | Vaginal hysterectomy, for uterus greater than 250 g; |
| 58291 | ; with removal of tube(s) and/or ovary(s) |
| 58292 | ; with removal of tube(s) and/or ovary(s), with repair of enterocele |
| 58294 | ; with repair of enterocele |
| 58541 | Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; |
| 58542 | ; with removal of tube(s) and/or ovary(s) |
| 58543 | Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; |
| 58544 | ; with removal of tube(s) and/or ovary(s) |
| 58550 | Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; |
| 58552 | ; with removal of tube(s) and/or ovary(s) |
| 58553 | Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; |
| 58554 | ; with removal of tube(s) and/or ovary(s) |
| 58570 | Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; |
| 58571 | ; with removal of tube(s) and/or ovary(s) |
| 58572 | Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; |
| 58573 | ; with removal of tube(s) and/or ovary(s) |
| 58575 | Laparoscopy, surgical, total hysterectomy for resection of malignancy (tumor debulking), with omentectomy including salpingo-oophorectomy, unilateral or bilateral, when performed |

HCPSC CODES

No specific codes identified

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Hysterectomy/Oophorectomy, continued

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Revision History

| Revision Date | Summary of Changes |
|---------------|--|
| 1/19/23 | For Commercial Plan Policy, added language to criterion #A-1k: " Uterine sarcoma" to clarify this requirement. |
| 2/9/23 | For Commercial Plan Policy, added table explaining Staging of Pelvic Organ Prolapse to help clarify qualifying indications for meeting criterion #6d. |
| 7/10/23 | For Commercial Plan Policy, modified definitions of criterion #A-1a and #A-1b (endometrial hyperplasia with cellular atypia [and without cellular atypia], respectively) to align with updated clinical definitions. |
| 11/13/23 | For Commercial Plan Policy, added new criterion #A-1j: "RAD51C/RAD51D (with oophorectomy)" as a qualifying indication for cancer, precancerous, or high cancer risk patients. |
| 12/1/23 | For Commercial Plan Policy, modified criterion #d in Oophorectomy Criteria section (section B): "Genetic mutation confirmed by molecular testing for breast and ovarian cancer susceptibility genes (ATM, BRCA1, BRCA2, BRIP1, Lynch syndrome genes [MLH1, MSH2, MSH6, EPCAM, PMS2], PALB2, RAD51C, and RAD51D)," to match corresponding section in medical policy #448 (Prophylactic Oophorectomy/Salpingo Oophorectomy). |
| 12/9/24 | For Commercial Plan Policy, modified criterion #4e: "Abnormal bleeding associated with |

Hysterectomy/Oophorectomy, continued

| | |
|---------|---|
| | <i>leiomyomas</i> [was previously: "Abnormal bleeding associated <i>with submucous fibroids not resectable by hysteroscopy</i> ". |
| 4/24/25 | Retitled policy as "Hysterectomy/Oophorectomy" (was previously titled as just "Hysterectomy"), and for Commercial Plan Policy, modified overall coverage criteria to align with current clinical standards, including adding separate sections of guidelines abnormal uterine bleeding and revising requirements for uterine prolapse. |
| 6/5/25 | For Commercial Plan Policy, updated requirements in criteria section #I-I (Uterine Prolapse); and added chart for help with classifying pelvic organ prolapse in this section. |
| 6/10/25 | For Commercial Plan Policy, clarified requirements in criteria section #I-E: "Adenomyosis by clinical history and exam, with failure of NSAIDs > 12 weeks (if tolerated), and any one of the following: i. Hormone therapy > 12 weeks; or ii. LNG-IUS (Levonorgestrel-containing Intrauterine system) > 12 weeks; or iii. Tranexamic acid > 12 weeks; or iv. GnRH agonist > 12 weeks; or v. Uterine artery embolization. " |
| 7/7/25 | For Commercial Plan Policy, clarified requirements in criteria section #I-H: "Endometriosis by laparoscopy with uterine involvement, and has failed any of the following therapies for > 12 weeks within the last 5 years: i. GnRH (Gonadotropin-releasing hormone) agonist; or ii. GnRH antagonist; or iii. Danocrine (Danazol); or iv. LNG-IUS (Levonorgestrel-containing Intrauterine system); or v. Hormone therapy." |

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LAPAROSCOPIC RADIOFREQUENCY ABLATION OF UTERINE FIBROIDS

Policy # 650

Implementation Date: 12/1/21

Review Dates: 6/14/24, 6/18/25

Revision Dates:

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Laparoscopic radiofrequency ablation is a minimally invasive treatment option for the management of symptomatic leiomyomas in patients who desire uterine preservation. There is limited available data on reproductive outcomes after this procedure, so women should be counseled appropriately prior to the procedure if they desire future fertility. Radiofrequency ablation (RFA) is delivered by a laparoscopic approach, using ultrasound guidance to induce coagulative necrosis in targeted uterine leiomyomas. Patients typically have shorter recovery times and require less pain management than other minimally invasive techniques for treatment of fibroids, such as hysterectomy and myomectomy.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health considers laparoscopic radiofrequency ablation for the treatment of uterine fibroids in women age 18 and older to be medically necessary when ALL the following conditions are met:

1. Evidence of uterine fibroids via ultrasound that are less than 10 cm in diameter; and
2. Member desires a uterine-sparing treatment approach, or is contraindicated for hysterectomy; and
3. Member has experienced any one of the following symptoms that are a direct result of the fibroid(s):
 - a) Menorrhagia interferes with daily activities or causes anemia; or
 - b) Pelvic pain or pressure, or
 - c) Lower back pain; or
 - d) Urinary symptoms (e.g., urinary frequency, urgency) related to compression of the bladder; or
 - e) Gastrointestinal symptoms related to compression of the bowel (e.g., constipation, bloating)

Select Health considers laparoscopic techniques of myolysis in any other circumstance, including but not limited to, MRI laser ablation, cryomyolysis, or the use of laser ablation using bipolar needles, to be experimental/investigational.



Laparoscopic Radiofrequency Ablation for Uterine Fibroids, continued

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Billing/Coding Information

CPT CODES

58674 Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency

Key References

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MEDICAL POLICY

LAPAROSCOPIC UTERINE NERVE ABLATION (LUNA) PRESACRAL NEURECTOMY (PSN)

Policy # 440

Implementation Date: 3/17/10

Review Dates: 4/21/11, 8/16/11, 8/16/12, 8/15/13, 8/28/14, 8/20/15, 8/25/16, 8/17/17, 7/16/18, 6/20/19, 6/18/20, 6/17/21, 5/19/22, 6/15/23, 6/14/24, 6/18/25

Revision Dates:

Disclaimer:

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Chronic pelvic pain (CPP) refers to pain of at least 6 months' duration that occurs below the navel and is severe enough to cause functional disability or require treatment. In the United States, this problem accounts for approximately 10% of all referrals to a gynecologist and is a common indication for diagnostic and therapeutic surgery. It is considered the principal indication for approximately 20% of hysterectomies performed for benign disease and at least 40% of gynecological laparoscopies.

Common causes of pelvic pain include endometriosis, chronic pelvic inflammatory disease, and dysmenorrhea. Chronic pelvic pain due to a gynecologic condition is often treated medically. In some cases, however, surgery may be the treatment of choice. Hysterectomy may alleviate chronic pelvic pain, especially when it is due to uterine disorders such as adenomyosis or fibroids. However, pain can persist even after hysterectomy, particularly in younger women (those less than age 30) and in women with a history of chronic pelvic inflammatory disease or pelvic floor dysfunction. Hysterectomy is not a good choice for the management of chronic pelvic pain in women who have not completed their family.

The use of nerve transection procedures has been investigated for the treatment of chronic pelvic pain. They are often carried out during other surgical treatments for endometriosis. The most common of these nerve transection procedures are laparoscopic uterine nerve ablation (LUNA) and presacral neurectomy (PSN). Laparoscopic uterine nerve ablation involves the destruction of the uterine nerve fibers that exit the uterus through the uterosacral ligament. Presacral neurectomy refers to the interruption of the sympathetic innervation of the uterus at the level of the superior hypogastric plexus. Presacral neurectomy is technically more challenging than LUNA because of the presence of large vessels and the ureters near the field of dissection. LUNA is often carried out during other surgical treatment for endometriosis.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does **NOT** cover laparoscopic uterine nerve ablation (LUNA) or presacral neurectomy (PSN) as current evidence demonstrates this treatment to meet the plan's definition of experimental/investigational.

Laparoscopic Uterine Nerve Ablation (LUNA); Presacral Neurectomy (PSN), continued

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

Review of the peer-reviewed literature revealed only one systematic review on either LUNA or PSN in the treatment of chronic pelvic pain. This Cochrane review on treatment of chronic pelvic pain in women found that: "LUNA is not shown to be effective."

The National Institute for Health and Clinical Excellence (NICE) in their 2007 assessment of the technology concluded: "[T]he evidence on laparoscopic uterine nerve ablation (LUNA) for chronic pelvic pain suggests that it is not efficacious and therefore should not be used."

Additionally, review of the peer-reviewed literature identified only 3 randomized controlled trials using PSN along with other surgical treatment of endometriosis. One of these randomized controlled trials compared the outcomes of PSN to LUNA. In this trial of 68 patients with primary dysmenorrhea assigned to either PSN or LUNA, Chen et al. reported that both groups were equal in terms of symptom relief (87.9% vs. 89.9%), but the efficacy of PSN was better than LUNA at 12 months (81.8% vs. 51.4%).

Specific to PSN, Tjaden et al. (1990) found that the addition of PSN to standard surgical therapy by laparotomy enhanced pain relief for midline pain. However, only 8 of 26 patients were randomized and the study was terminated before completion because of significant reduction in midline pain by the patients undergoing PSN. Another study by Candiani et al. randomly assigned 71 women with moderate-to-severe endometriosis and midline dysmenorrhea to conservative surgery alone or conservative surgery with PSN. The addition of PSN markedly reduced the midline component of menstrual pain, but no statistically significant differences were observed between the 2 groups in the frequency and severity of dysmenorrhea, pelvic pain, and dyspareunia in the long-term follow-up. Furthermore, constipation developed or worsened in 13 of 35 patients and urinary urgency developed in 3. The authors concluded that PSN should be considered only in selected cases (e.g., women with severe incapacitating dysmenorrhea, recurrent disease, or symptoms that did not respond to initial treatment).

Finally, in a trial performed by Zullo et al., 141 women aged 26–39 years with severe dysmenorrhea due to endometriosis to laparoscopic electrocautery ablation or excision, enucleation of endometriomas, lysis of adhesions, and uterosacral ligament resection of deep ligamentous lesions (group A), or these treatments plus PSN (group B) were randomly assigned. The addition of PSN significantly improved cure rates (defined as significant relief of dysmenorrhea) at both 6 months (87% vs. 60%) and 12 months (86% vs. 57%); the improvement occurred across all stages. Although the severity of dysmenorrhea, dyspareunia, and pelvic pain was lower in group B than group A, there was no difference between groups in the frequency of these symptoms. Surgical complications were uncommon and equivalent; constipation and urgency only occurred in women who had PSN (at 12 months: constipation 14 % and urgency 5%). Of note, conservative surgery alone (i.e., without PSN) led to most of the reduction in severity of dysmenorrhea, as measured by a visual analog scale (baseline score: 82, after conservative surgery: 54, after conservative surgery and PSN: 46). The authors concluded that PSN with conservative surgery was an effective treatment for pelvic pain related to endometriosis.

Laparoscopic Uterine Nerve Ablation (LUNA); Presacral Neurectomy (PSN), continued

A randomized control trial by Daniels et al. published in 2009 for LUNA did not identify any improvement in outcomes in the LUNA treated groups compared to matched controls not undergoing LUNA for chronic pelvic pain. After a median follow-up of 69 months, there were no significant differences reported on the visual analogue pain scales for the worst pain. Additionally, no differences were observed between the LUNA group and the no LUNA group related to quality of life. The authors concluded that among women with chronic pelvic pain, LUNA did not result in improvements in pain, dysmenorrhea, dyspareunia, or quality of life compared with laparoscopy without pelvic denervation.

A review in an article titled, "Chronic Pelvic Pain," Steege and Siedhoff (Obstetrics and Gynecology, September 2014, Volume 124(3): p. 616-629), the authors do not even mention LUNA as a viable option for the treatment of chronic pelvic pain. However, they do discuss PSN and reference the following article: "Zullo et al investigated the question with a double-masked randomized trial and demonstrated a 20% difference in pain improvement when PSN was added to endometriosis excision in women with a midline component to their pain."

Billing/Coding Information

CPT CODES

- 49329** Unlisted laparoscopy procedure, abdomen, peritoneum and omentum
58578 Unlisted laparoscopy procedure, uterus

HCPCS CODES

- C1886** Catheter, extravascular, tissue ablation, any modality (insertable)

Key References

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Laparoscopic Uterine Nerve Ablation (LUNA); Presacral Neurectomy (PSN), continued

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NON-MEDICALLY INDICATED (ELECTIVE) INDUCTION OF LABOR BEFORE 39 WEEKS GESTATIONAL AGE

Policy # 572

Implementation Date: 8/24/15

Review Dates: 10/20/16, 10/19/17, 10/15/18, 10/15/19, 10/15/20, 7/18/22, 9/4/23, 9/19/24

Revision Dates: 12/29/22

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1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Induction of labor is the artificial start of the birth process through medical interventions or other methods. Elective induction is defined as induction of labor when there is no clear medical benefit to the mother or child for delivery at that point in time compared with continuation of pregnancy. Every week of gestation matters for the health of newborns. On average, a pregnancy with a single fetus lasts 40 weeks from the first day of the last menstrual period. The last few weeks of pregnancy within these 40 weeks allow a baby's brain and lungs to fully mature. Babies born between 39 weeks 0 days and 40 weeks 6 days gestation, have the best health outcomes, compared with babies born before or after this period. This distinct period is now referred to as "full-term." The following represent the four definitions of 'term' deliveries:

- Early-Term: 37 weeks 0 days to 38 weeks 6 days
- Full-Term: 39 weeks 0 days to 40 weeks 6 days
- Late-Term: 41 weeks 0 days to 41 weeks 6 days
- Post-Term: Between 42 weeks 0 days and beyond

When labor doesn't start naturally, there are many methods providers can use to get labor going. Pitocin, the synthetic version of the hormone oxytocin, which a woman's body produces to start uterine contractions, can be used. It is given through an IV and dosage can be adjusted. Pitocin works best when the cervix is favorable, meaning it's dilated, effaced (soft), and in an anterior position. There is also a concern that Pitocin makes contractions very strong, but it varies from woman to woman, and this could also be the case with natural labor. Another induction procedure is artificial rupture of membranes (AROM), which might help, although Pitocin is often given as well. Prostaglandin medications like Cytotec and Cervidil help to soften the cervix and in some women, it may also cause contractions. These medications may not work if the baby is preterm and if the cervix is not favorable. Unlike Cervidil, which can be removed if the uterus hyper-stimulates or the contractions are too close together, Cytotec dissolves in the body. Providers can also insert a Foley catheter balloon filled with sterile water into the cervix to mechanically dilate it and cause a release of prostaglandins. Providers can also "strip the membranes," by inserting a finger through the cervix and moving it side to side to release prostaglandins. This procedure can be painful and there is no guarantee with either method that labor will start.

As with any medical procedure, induction comes with risks. If a woman's cervix is unfavorable, the risk of having a cesarean is 30 percent. If the cervix is favorable, the risk is the same as natural childbirth. Elective inductions before 39 weeks could pose problems for babies whose lungs are not fully mature. Other risks include fetal distress, infection for both mom and baby, umbilical cord problems, uterine rupture, and hemorrhage. Moreover, a recent study out of Beth Israel Medical Center found that induction

Non-Medically indicated (Elective) Induction of Labor before 39 Weeks Gestational Age, continued

with Pitocin increased the risk that newborns would be unexpectedly admitted into the NICU and have lower Apgar scores. Even though induction is meant to jump-start labor, it doesn't necessarily speed it up.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers elective induction of labor prior to 39 weeks in limited circumstances, when criteria are met, which define the services being medically necessary.

Criteria for coverage of delivery prior to 39 weeks (must have ANY ONE of the following medical indications):

1. Placenta Abruption
2. Placenta Previa
3. PROM (premature rupture of membranes)
4. Chorioamnionitis
5. Maternal medical indication:
 - a. Preeclampsia: BP \geq 140/90 with \geq 1+ proteinuria
 - b. Severe Preeclampsia: includes HELLP
 - c. Eclampsia
 - d. Coagulation defects (e.g., thrombocytopenia, von Willebrand's disease, hemophilia)
 - e. Diabetes (pre-gestational and gestational)
 - f. Chronic renal disease (e.g., renal insufficiency, proteinuria)
 - g. Antiphospholipid syndrome
 - h. SLE with documented comorbidity or lupus anticoagulant
 - i. Prior classical incision or myomectomy
 - j. Gestational hypertension: elevated BP of \geq 140/90
 - k. Chronic hypertension: BP $>$ 140/90
 - l. Liver and biliary disease
 - m. Intrahepatic cholestasis of pregnancy (documentation of lab and medication is required)
 - n. HIV, only if viral load $>$ 1000 copies and intact membranes (well-managed HIV can be term)
 - o. Maternal cardiac disease
 - p. Alloimmunization/RH sensitized or other RBC antigen sensitization
 - q. Maternal-fetal hemorrhage
 - r. Other moderate to severe maternal medical conditions (MFM approved required)
 - s. Prior uterine rupture
 - t. Hypertension
6. Fetal Indications
 - a. Fetal growth restriction $<$ 10th percentile (documentation required)
 - b. Oligohydramnios (AFI 5 cm or DVP $<$ 2) (documentation required)

Non-Medically indicated (Elective) Induction of Labor before 39 Weeks Gestational Age, continued

- c. Polyhydramnios (AFI > 30 cm) (documentation required)
- d. Multiple gestation
- e. Abnormal antenatal testing
- f. Fetal demise
- g. Previous stillbirth (poor reproductive history)
- h. Severe congenital anomalies
- i. Unstable lie (> 38 weeks)
- j. Fetal damage (radiation/drug/virus exposure)
- k. Other indications (documentation required) (name of MFM physician that was consulted)
- l. Abnormal umbilical artery
- m. Alloimmunization

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

Efforts to improve the quality and safety of perinatal care have received increased focus during recent years. Research has shown that elective early-term delivery without medical or obstetrical indication is linked to neonatal morbidities and has no benefit to the mother or infant. The American College of Obstetricians and Gynecologists (ACOG) publications have consistently advised against non-medically indicated elective deliveries prior to 39 weeks gestation. Despite ACOG guidelines, elective early-term labor inductions and cesarean sections are common, and increasing in the United States, and are creating concern about trends in current obstetric practice. Educating healthcare providers about morbidities associated with practice trends fosters evidence-based decision-making and leads to improved practices that reduce harm.

ACOG and the Society for Maternal-Fetal Medicine have long discouraged nonindicated delivery before 39 weeks of gestation. The reason for this longstanding principle is that the neonatal risks of late-preterm (34 0/7–36 6/7 weeks of gestation) and early-term (37 0/7–38 6/7 weeks of gestation) births are well established. However, there are a number of maternal, fetal, and placental complications in which either a late-preterm or early-term delivery is warranted. The timing of delivery in such cases must balance the maternal and newborn risks of late-preterm and early-term delivery with the risks of further continuation of pregnancy.

There are several important principles to consider in the timing of delivery. First, the decision-making regarding timing of delivery is complex and must take into account relative maternal and newborn risks, practice environment, and patient preferences. Second, late-preterm or early-term deliveries may be warranted for either maternal or newborn benefit or both. In some cases, healthcare providers will need to weigh competing risks and benefits for mother and newborn; therefore, decisions regarding timing of

Non-Medically indicated (Elective) Induction of Labor before 39 Weeks Gestational Age, continued

delivery must be individualized. Additionally, recommendations such as these are dependent on accurate determination of gestational age.

Further, ACOG has stated that a mature fetal lung maturity profile is not an indication for delivery in the absence of other clinical indications. Yet, the rate of non-medically indicated early-term (37 0/7–38 6/7 weeks of gestation) deliveries continues to increase in the United States. In contrast, the late-preterm (34 0/7–36 6/7 weeks of gestation) birth rate, which increased 25% from 1990 to 2006, has leveled off and started a slow decrease from 9.1% in 2006 to 8.8% in 2008. There are medical indications in pregnancy for which there is evidence or expert opinion to support expedient delivery in the early-term period versus expectant management. In contrast, suspected macrosomia and documented pulmonary maturity with no other indication are all examples of conditions that are not indications for an early-term delivery.

Bailey et al. (2014) reported that infants delivered at ≥ 37 weeks' gestation are considered full-term, but research has demonstrated those born at 37 to 38 weeks (early-term) have a higher risk for poor birth outcomes than deliveries at 39 to 41 weeks (full-term). Despite this, many deliveries occur electively (scheduled, no medical indication) before 39 weeks. This study examined the risks of elective early-term delivery in a disadvantaged, rural sample, and compared these results with national findings. Data were available for 638 rural women, recruited prenatally from three counties in rural southern Appalachia, who delivered electively at ≥ 37 weeks. Compared with electively-delivered full-term infants, those delivered electively at early term were 7.7 times more likely to be low birth weight, 4.4 times more likely to have a neonatal intensive care unit admission, and 2.5 times more likely to develop jaundice. Those living farthest from the hospital were most likely to deliver electively at < 39 weeks. Although rates of elective deliveries < 39 weeks were no higher than national rates, adjusted odds ratios (aOR) of associated admission to a neonatal intensive care unit doubled (aOR 4.4 vs aOR 2.2). The authors concluded results demonstrate that initiatives targeting early-term elective deliveries are needed in rural, disadvantaged regions.

Berrien et al. (2014) reported that despite longstanding guidelines from the American College of Obstetricians and Gynecologists that call for avoiding elective births prior to 39 weeks of gestation, elective deliveries make up almost one-third of US births occurring in weeks 36–38. Poor outcomes are more likely for infants born electively before 39 weeks than for those born at 39 weeks. The Perinatal Quality Collaborative of North Carolina (PQCNC) undertook the 39 Weeks Project in 2009–2010 with the aim of reducing the number of early-term elective deliveries in North Carolina hospitals. Participating hospitals ($N = 33$) provided retrospective data on all early-term deliveries and created new policies, or amended or enforced existing policies, to accomplish the project's goals. Project activities included in-person learning sessions, regional meetings, webinars, electronic newsletters, a secure extranet web site where participating hospitals could share relevant materials, and individual leadership consultations with hospital teams. Hospitals submitted monthly data to PQCNC, which provided ongoing training and data analysis. Elective deliveries before 39 weeks of gestation decreased 45% over the project period, from 2% to 1.1% of all deliveries. The proportion of elective deliveries among all scheduled early-term deliveries also decreased, from 23.63% to 16.19%. There was an increase in the proportion of patients with documented evidence of medical indications for early delivery, from 62.4% to 88.2%. Two limitations of the study were that no data were collected to determine whether outcomes changed for patients whose deliveries were deferred and that each hospital was depended upon to code their own data. The authors concluded the PQCNC's 39 Weeks Project successfully decreased the rate of early-term elective deliveries in participating hospitals.

Gibson et al. (2014) evaluated the mode of delivery as well as maternal and neonatal morbidities in low-risk patients whose labor was electively induced, or expectantly managed at term, in a retrospective cross-sectional study from 12 US institutions (19 hospitals, 2002 through 2008 [Safe Labor Consortium]). Healthy women with viable, vertex singleton pregnancies at 37–41 weeks of gestation were included. Women electively induced in each week were compared with women managed expectantly. The primary outcome was mode of delivery. Of 131,243 low-risk deliveries, 13,242 (10.1%) were electively induced. The risk of cesarean delivery was lower at each week of gestation with elective induction vs. expectant management regardless of parity and modified Bishop score (for unfavorable nulliparous patients at: 37 weeks = 18.6% vs 34.2%, adjusted odds ratio, 0.40; [95% confidence interval, 0.18-0.88]; 38 weeks = 28.4% vs 35.4%, 0.65 [0.49-0.85]; 39 weeks = 23.6% vs 38.5%, 0.47 [0.38-0.57]; 40 weeks = 32.3% vs 42.3%, 0.70 [0.59-0.81]). Maternal infections were significantly lower with elective inductions. Major, minor, and respiratory neonatal morbidity composites were lower with elective inductions at ≥ 38 weeks

Non-Medically indicated (Elective) Induction of Labor before 39 Weeks Gestational Age, continued

(for nulliparous patients at: 38 weeks = adjusted odds ratio, 0.43; [95% confidence interval, 0.26-0.72]; 39 weeks = 0.75 [0.61-0.92]; 40 weeks = 0.65 [0.54-0.80]).

The authors concluded elective induction of labor at term is associated with decreased risks of cesarean delivery and other maternal and neonatal morbidities compared with expectant management regardless of parity or cervical status on admission.

Parikh et al. (2014) examined the timing of elective delivery and neonatal intensive care unit (NICU) utilization of electively delivered infants from 2008 to 2011. Analysis included 42,290 women with singleton gestation enrolled in a pregnancy education program, reporting uncomplicated pregnancies with elective labor induction (ELI) (n=27,677), or scheduled cesarean delivery (SCD) (n=14,613) at 37.0-41.9 weeks' gestation. Data were grouped by type and week of delivery (37.0-37.9, 38.0-38.9, and 39.0-41.9 weeks). ELI and SCD for each week of delivery from 2008 to 2011 and nursery utilization by delivery week were compared. During the 2008-2011 timeframe, a shift in timing of ELI and SCD toward ≥ 39.0 weeks was observed. In 2008, 80.9% of ELI occurred at ≥ 39.0 weeks versus 92.6% in 2011 ($p < 0.001$). In 2008, 60.5% of SCD occurred at ≥ 39.0 weeks versus 78.1% in 2011 ($p < 0.001$). NICU admission and prolonged nursery stays were highest at 37.0-37.9 weeks for both groups. The authors concluded they observed a shift toward later gestational age at elective delivery from 2008 to 2011 and increased NICU utilization for neonates born at < 39 weeks' gestation.

Finally, Groban et al (2019)., in a meta-analysis, found that delivery after 39 weeks when compared to prior to 39 weeks (without risk factors) was associated with a significantly lower risk of cesarean delivery, maternal peripartum infection, and perinatal adverse outcomes, including respiratory morbidity, intensive care unit admission, and mortality.

Billing/Coding Information**CPT CODES**

| | |
|--------------|---|
| 59400 | Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care |
| 59409 | Vaginal delivery only (with or without episiotomy and/or forceps); |
| 59410 | Vaginal delivery only (with or without episiotomy and/or forceps); including postpartum care |
| 59510 | Routine obstetric care including antepartum care, cesarean delivery, and postpartum care |
| 59514 | Cesarean delivery only |
| 59515 | Cesarean delivery only; including postpartum care |
| 59525 | Subtotal or total hysterectomy after cesarean delivery (List separately in addition to code for primary procedure) |
| 59612 | Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps) |
| 59614 | Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps); including postpartum care |
| 59610 | Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery |

HCPC CODES

No specific codes identified

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Non-Medically indicated (Elective) Induction of Labor before 39 Weeks Gestational Age, continued

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MEDICAL POLICY

OVA1 TUMOR TRIAGE TEST

Policy # 411

Implementation Date: 3/26/09

Review Dates: 4/22/10, 2/17/11, 2/16/12, 4/25/13, 2/20/14, 3/19/15, 2/11/16, 2/16/17, 2/15/18, 2/4/19, 2/17/20, 2/18/21, 1/3/22, 8/30/23, 2/5/25

Revision Dates: 9/1/23

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Ovarian cancer accounts for about 3% of all cancers among women and is the second most common gynecologic malignancy, next to endometrial carcinoma. Clinical symptoms at early stages are rare, however, and diagnosis is often made at advanced tumor stages.

In gynecology, the adnexa refer to the region adjoining the uterus that contains the ovary and fallopian tube, as well as associated vessels, ligaments, and connective tissue. Pathology in this area may also arise from the uterus, bowel, retroperitoneum, or metastatic disease from another site, such as the breast or stomach. Prevalence of an adnexal mass varies widely depending upon the population studied and the criteria employed to define it.

The clinical significance of discriminating benign from malignant masses differs depending on the clinical setting in which the mass is initially detected. In women who initially present with symptoms, diagnosis of the underlying cause of the mass is important since it may help define available treatment options. Although medical therapy may relieve symptoms in some cases, surgical management is the treatment of choice for many conditions. Because surgery may ultimately be the most appropriate management for symptomatic adnexal masses, the main reason to discriminate between benign and malignant lesions is to facilitate referral and management by clinicians with specialized training and experience in managing ovarian malignancy, due to improved outcomes.

The OVA1 test (Vermillion, Inc.; Fremont, California), is a proprietary statistical model (i.e., a multivariable regression algorithm), referred to as OvaCalc, and applied to the following panel of 5 biomarkers: apolipoprotein A1, beta-2 microglobulin ($\beta 2M$), CA125, transferrin (Tfr), and transthyretin (TT).

OvaCalc software is used to import the values for TT, Apo A-1, $\beta 2M$, Tfr, and CA 125 to reconcile and numerically combine the values from the five biomarker assays and use the OVA1 algorithm to generate an ovarian malignancy risk index score for each individual specimen. The output of the OVA1 algorithm is a numeric index between 0.0 and 10.0. Cut-off values at 5.0 for pre-menopausal women and at 4.4 for post-menopausal women were determined based on the training data. The cutoff value classifies a patient based on her OVA1 test score.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover the OVA1, OVERA (MIA2G), or Risk of Ovarian Malignancy Algorithm (ROMA) tests due to both a lack of clinical data, as well as a lack of FDA recommendation, to support the use of these tests as a screening tool for ovarian cancer. This meets the plan's definition of experimental/investigational.

OVA1 Tumor Triage Test, continued

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

The decision whether to proceed with surgical evaluation for a patient with an adnexal mass depends mostly upon the appearance of the mass on imaging and other factors, rather than on a biomarker test.

The main biomarker that has been studied for use in the initial evaluation of an adnexal mass is cancer antigen 125 (CA 125), although this is not its US Food and Drug Administration-approved indication. OVA1 has only been studied in patients for whom surgery has already been planned and thus likely have a higher prevalence of ovarian cancer than the general population of patients with an ovarian tumor. In the absence of data regarding the use of OVA1 in the initial evaluation of an adnexal mass, the use of this test to decide whether to proceed with surgical exploration for an adnexal mass is not recommended.

There are a number of biomarker tests and prediction algorithms (based on a variety of factors, such as symptoms, imaging results, biomarkers, and patient characteristics) that have been developed for assessing the likelihood of malignancy among patients who have an adnexal mass (and have not yet had surgery). It is important to note that these tests are for preoperative assessment only, and none is suitable for ovarian cancer screening prior to detection of an adnexal mass; they are also not for use as stand-alone diagnostic tests. For example, the OVA1 test is a multivariate index assay (MIA) that uses five markers (including transthyretin, apolipoprotein A1, transferrin, beta-2 microglobulin, and CA-125) in preoperative serum to assess the likelihood of malignancy in patients with an adnexal mass for which surgery is planned, with the aim of helping community practitioners determine which patients to refer to a gynecologic oncologist for evaluation and surgery. The Society of Gynecologic Oncology (SGO) and the FDA have stated that the OVA1 test should not be used as a screening tool to detect ovarian cancer in patients without any other signs of cancer, or as a stand-alone diagnostic tool. Moreover, based on data documenting an increased survival, the NCCN Guidelines Panel recommends that all patients with suspected ovarian malignancies (especially those with an adnexal mass) should undergo evaluation by an experienced gynecologic oncologist prior to surgery.

A number of specific biomarkers and algorithms using multiple biomarker test results have been proposed for preoperatively distinguishing benign from malignant tumors in patients who have an undiagnosed adnexal/pelvic mass. Biomarker tests developed and evaluated in prospective trials comparing preoperative serum levels to postoperative final diagnosis include serum HE4 and CA-125, either alone or combined using the Risk of Ovarian Malignancy Algorithm [ROMA] algorithm; the MIA (brand name OVA1) based on serum levels of five markers: transthyretin, apolipoprotein A1, transferrin, beta-2 microglobulin, and CA-125; and the second-generation MIA (MIA2G, branded name OVERA) based on CA-125, transferrin, apolipoprotein A1, follicle-stimulating hormone [FSH], and HE4. The FDA has approved the use of ROMA, OVA1, or OVERA for estimating the risk for ovarian cancer in those with an adnexal mass, for which surgery is planned, and have not yet been referred to an oncologist.

OVA1 Tumor Triage Test, continued

Although the American Congress of Obstetricians and Gynecologists (ACOG) has suggested that ROMA and OVA1 may be useful for deciding which patients to refer to a gynecologic oncologist, other professional organizations have been non-committal. Not all studies have found that multi-biomarker assays improve all metrics (i.e., sensitivity, specificity, positive predictive value, negative predictive value) for prediction of malignancy compared with other methods (e.g., imaging, single-biomarker tests, symptom index/clinical assessment).

Currently, the NCCN Panel does not recommend the use of these biomarker tests for determining the status of an undiagnosed adnexal/pelvic mass.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

- 81500** Oncology (ovarian), biochemical assays of two proteins (CA-125 and HE4), utilizing serum, with menopausal status, algorithm reported as a risk score
- 81503** Oncology (ovarian), biochemical assays of five proteins (CA-125, apolipoprotein A1, beta-2 microglobulin, transferrin, and pre-albumin), utilizing serum, algorithm reported as a risk score
- 84999** Unlisted chemistry procedure

HCPCS CODES

No specific codes identified

Key References

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Revision History

| Revision Date | Summary of Changes |
|---------------|--|
| 9/1/23 | For Commercial Plan Policy, added the OVERA (MIA2G) and Risk of Ovarian Malignancy Algorithm (ROMA) tests to list of excluded tests. |

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OVA1 Tumor Triage Test, continued

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MEDICAL POLICY

PROPHYLACTIC OOPHORECTOMY/SALPINGO OOPHORECTOMY

Policy # 448

Implementation Date: 7/12/10

Review Dates: 8/16/11, 8/16/12, 8/15/13, 8/28/14, 8/20/15, 8/25/16, 8/17/17, 8/7/18, 10/15/19, 10/15/20, 11/30/21, 1/13/23, 12/21/23, 2/5/25

Revision Dates: 9/7/16, 8/7/18, 1/29/19, 12/5/22, 11/13/23, 12/1/23

Related Medical Policies:

[#620 Hysterectomy](#)**Disclaimer:**

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Ovarian cancer is the leading cause of death in the U.S. from gynecological malignancies and is the second most common gynecological cancer in women. Unfortunately, only about 25% of patients are diagnosed when ovarian cancer is still localized to the ovary, when treatment success is high. Up to 90% of these very early cancers can be successfully treated, while only 30% of the patients with more advanced cancers will survive 5 years. All women are at risk for ovarian cancer, but older women are more likely to get the disease than younger women. About 90% of women who get ovarian cancer are older than 40, with the greatest number being age 55 or older.

Prophylactic bilateral oophorectomy has been recommended for women at high risk of ovarian cancer. The term "hereditary ovarian cancer syndrome" refers to three rare cancer syndromes, which occurs in approximately 5% of all ovarian cancers. These are: breast-ovarian cancer syndrome, site-specific cancer syndrome, and hereditary non-polyposis colorectal cancer syndrome (Lynch syndrome I). Breast-ovarian syndrome occurs in families with clusters of women with ovarian cancer and/or breast cancer. Site-specific ovarian cancer syndrome occurs in families with clusters of ovarian cancer. Lynch syndrome I is a familial cancer syndrome characterized by an inherited predisposition to the development of the early onset (usually ages 40–50) of adenocarcinomas of the colon with proximal colonic predominance, ovary, pancreas, breast, bile duct, cervix, endometrium, and of the urologic (most commonly ureter and renal pelvis) and gastrointestinal systems.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers prophylactic oophorectomy or salpingo-oophorectomy in *limited* circumstances.

Criteria for coverage (at least one must be present):

1. Endometrial cancer is present; or
2. Genetic mutation confirmed by molecular testing for breast and ovarian cancer susceptibility genes (ATM, BRCA1, BRCA2, BRIP1, Lynch syndrome genes [MLH1, MSH2, MSH6, EPCAM, PMS2], PALB2, RAD51C, and RAD51D); or
3. Known familial cancer syndrome associated with increased risk of ovarian cancer. This includes breast cancer and hereditary nonpolyposis colon cancer (HNPCC) (includes Lynch syndrome); after completion of childbearing; or

Prophylactic Oophorectomy/Salpingo Oophorectomy, continued

4. Premenopausal woman with estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+) breast cancer.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website <http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

Summary of Medical Information

The lifetime probability of ovarian cancer increases from about 1.6% in a 35-year-old woman without a family history of ovarian cancer to about 5% if she has one relative with ovarian cancer, and to about 7% if she has two relatives with ovarian cancer. Out of those patients who have a positive family history, 3–9% may end up having hereditary cancer syndromes. Epithelial ovarian cancer, the most common histopathologic type, is uncommon in women before the age of 40. The incidence rates then increase steeply until a woman reaches her seventies, then decrease somewhat. About 7% of women with ovarian cancer report a family history of ovarian cancer, and of these women, over 90% have only one relative with ovarian cancer.

Numerous studies have found that women at inherited risk of breast and ovarian cancer have a decreased risk of ovarian cancer following prophylactic oophorectomy. The available evidence evaluating the impact of prophylactic oophorectomy on individuals at high risk for ovarian cancer includes systematic reviews, case-control, and cohort studies. Women with BRCA mutations have a lifetime ovarian cancer risk of 13% or greater compared with 1.5% in the general population. For women in whom the risk falls below this level, there is no standard threshold regarding who should undergo elective oophorectomy.

There is no patient at greater risk of developing ovarian cancer than a woman in direct genetic lineage of a family with hereditary ovarian cancer syndrome. The probability of a hereditary ovarian cancer syndrome in a family pedigree increases with the number of affected relatives, with the number of affected generations, and with young age of onset of disease. Women suspected of having a hereditary ovarian cancer syndrome should have a family pedigree constructed by a physician or genetic counselor competent in determining the presence of an autosomal dominant inheritance pattern. The number of observed ovarian cancer-affected generations in ovarian cancer syndromes ranges from two to four per family. The sisters and daughters of a woman from a family with an ovarian cancer syndrome may have a lifetime probability as high as 50% of developing ovarian cancer. The mean age for ovarian cancer onset is 59 years for the general population, while that for various hereditary ovarian cancer syndromes is 52 years for breast-ovary, 49 years for site-specific ovary, and 45 years for Lynch I cases.

Observational studies have shown that women who have BRCA1 or BRCA2 mutations have higher risks for both ovarian cancer and breast cancer, and that prophylactic oophorectomy reduces the risk of both types of cancer. In a prospective follow-up study, researchers enrolled 170 eligible women (age 35 or older) with BRCA mutations who were referred for genetic counseling at Memorial Sloan-Kettering Cancer Center for 6 years. Ninety-eight women underwent bilateral prophylactic oophorectomy, and 72 chose surveillance (mean follow-up, 24 months). Among women who selected surveillance, breast cancer was diagnosed in 8, ovarian cancer in 4, and peritoneal cancer in 1. Among women who underwent prophylactic oophorectomy, breast cancer was identified subsequently in 3 and peritoneal cancers in 1; 3

Prophylactic Oophorectomy/Salpingo Oophorectomy, continued

early-stage ovarian cancers were found at surgery. The investigators reported that the hazard ratio for the development of breast or BRCA-related gynecologic cancer after oophorectomy was 0.25.

In a retrospective multicenter study, 6 of 259 BRCA-positive women were found to have stage I ovarian cancer at the time of prophylactic oophorectomy, and 2 subsequently developed peritoneal carcinomas. Among 292 matched controls that didn't undergo prophylactic surgery, 58 were diagnosed with ovarian cancer during a mean follow-up of 8.8 years. Thus, oophorectomy reduced the subsequent risk for ovarian or peritoneal cancer by 96%. In a subgroup analysis to determine breast-cancer risk, 21 of 99 women who underwent oophorectomy developed breast cancer compared with 60 of 142 controls (risk reduction, 53%).

Case-control and cohort studies (n = 170–1828) with median follow-up through 25 years have demonstrated that prophylactic oophorectomy is associated with a significant reduction in the risk of both ovarian and breast cancer. No definitive patient selection criteria have been established for prophylactic oophorectomy. However, there is sufficient evidence from cohort and case-control studies, and from decision analyses based on cumulative breast and gynecologic cancer incidence rates and survival data, to support the use of prophylactic oophorectomy as a primary breast and ovarian cancer prevention strategy in women who are confirmed BRCA1 or BRCA2 mutation carriers or who are members of a site-specific ovarian cancer family and who are over the age of 35 or who have completed childbearing.

The largest study to evaluate the degree of ovarian cancer risk reduction with oophorectomy at time of hysterectomy was a prospective observational study of 29,380 women age 30 or older who underwent hysterectomy with or without bilateral oophorectomy who participated in the Nurses' Health Study. Data were adjusted for family history of ovarian cancer and duration of oral contraceptive use. Women who did undergo oophorectomy had significant reductions in ovarian cancer incidence (hazard ratio 0.04, 95% CI 0.01–0.09; 305 vs. 339 cases per 100,000 person-year) and mortality (hazard ratio 0.06, 95% CI 0.02–0.21; 1 vs. 14 deaths per 100,000 person-year); this risk reduction was similar regardless of age at hysterectomy. The reduced risk of breast cancer that is associated with oophorectomy is likely due to reduced exposure to estrogen from the premenopausal ovary. As a result, the risk reduction varies by age at time of oophorectomy. Accordingly, the risk reduction varies by age at time of oophorectomy. The Nurses' Health Study report had data that were adjusted for family history of breast cancer and use of estrogen therapy. A significant reduction in breast cancer incidence was found only in women who underwent oophorectomy at less than 45 years old (hazard ratio 0.6, 95% CI 0.5–0.7; 222 vs. 315 cases per 100,000 person-year) and not in women 45 years or older. No significant difference in breast cancer mortality was found in any age group.

Despite the lack of randomized controlled trials (RCTs), the published, peer-reviewed medical literature indicates that prophylactic oophorectomy should be considered for premenopausal (age 35 or older), high-risk women (i.e., women known to carry the BRCA1 and/or BRCA2 mutation or to have a lineage of familial cancer). It is important that women undergoing prophylactic oophorectomy that this surgery does not eliminate the risk of developing cancer. Counseling regarding the risks and benefits of the procedure is equally important for women considering this preventive measure.

Ideal surgical management for risk-reducing salpingo-oophorectomy includes five steps outlined in 2005 by the Society of Gynecologic Oncology and the American College of Obstetricians and Gynecologists. These steps should include: (1) obtaining a complete survey of the peritoneal surfaces of the abdomen and pelvis, (2) collecting peritoneal washings for cytologic examination, (3) entering the retroperitoneal space to isolate and divide the ovarian pedicle 2 cm cephalad of identifiable ovarian tissue, (4) dividing the fallopian tubes and utero-ovarian ligaments as close to the uterus as possible, and (5) removing specimens in an endoscopic bag when the surgery is performed laparoscopically. In addition, it is recommended that pathologic examination include serial sectioning of specimens. The Sectioning and Extensively Examining the FIMbriated End (SEE-FIM) protocol involves longitudinal sectioning of the fimbria and extensive cross-sectioning of the remaining tube at 2-mm intervals. The SEE-FIM protocol has been shown to enhance the detection of premalignant and malignant lesions at the time of rrBSO. Adherence to the 5-step surgical protocol combined with SEE-FIM pathologic review has been shown to optimize the rate of detection of occult carcinoma at the time of risk reducing bilateral salpingo-oophorectomy.

Prophylactic Oophorectomy/Salpingo Oophorectomy, continued

The gynecologic literature confirms that women who are carriers of the germline mutation BRCA1 or BRCA2 are at the highest risk of ovarian cancer. According to Dr. Mark D. Pearlman in his article in *Obstetrics and Gynecology*, January 2013, Volume 121(1): pp. 4–6: "... careful pathologic examination of removed fallopian tubes and ovaries demonstrated that many of these 'ovarian cancers' actually originated in the fallopian tube. There is now general agreement that the fallopian tube is a major site of BRCA1-related and BRCA2-related malignancies. In fact, women who carry these gene mutations are at increased risk for tubal, ovarian, and primary peritoneal cancers, and the more encompassing term: 'pelvic serous cancers' has been proposed."

Billing/Coding Information

Covered: *For the conditions outlined above*

CPT CODES

| | |
|--------------|---|
| 58661 | Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy) |
| 58720 | Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate procedure) |
| 58940 | Oophorectomy, partial or total, unilateral or bilateral |
| 58943 | Oophorectomy, partial or total, unilateral or bilateral; for ovarian, tubal or primary peritoneal malignancy, with para-aortic and pelvic lymph node biopsies, peritoneal washings, peritoneal biopsies, diaphragmatic assessments, with or without salpingectomy(s), with or without omentectomy |

HCPCS CODES

No specific codes identified

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Prophylactic Oophorectomy/Salpingo Oophorectomy, continued

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Revision History

| Revision Date | Summary of Changes |
|---------------|---|
| 11/13/23 | For Commercial Plan Policy, updated breast and ovarian cancer susceptibility genes listed in criterion #2: "(ATM, BRCA1, BRCA2, BRIP1, Lynch syndrome genes [MLH1, MSH2, MSH6, EPCAM], PALB2, RAD51C, and RAD51D)." |
| 12/1/23 | For Commercial Plan Policy, added the PMS2 gene to list of eligible susceptibility genes in criterion #2. |

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