IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN; ZACHARY MARTELL; BRIAN MCNEMAR, SHAWN ANDERSON a/k/a SHAUNTAE ANDERSON; and LEANNE JAMES, individually and on behalf of all others similarly situated,

Plaintiffs,

Civil Action No. 3:20-cv-00740
Hon. Robert C. Chambers, Judge

v.

WILLIAM CROUCH, in his official capacity as Cabinet Secretary of the West Virginia Department of Health and Human Resources; **CYNTHIA BEANE,** in her official capacity as Commissioner for the West Virginia Bureau for Medical Services; **WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES; JASON HAUGHT,** in his official Capacity as Director of the West Virginia Public Employees Insurance Agency; and **THE HEALTH PLAN OF WEST VIRGINIA, INC.,**

Defendants.

DEFENDANTS' THIRD SUPPLEMENTAL RESPONSE TO PLAINTIFF'S FIRST SET OF REQUESTS FOR PRODUCTION TO DEFENDANTS WILLIAM CROUCH, CYNTHIA BEANE, AND WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES

DOCUMENT REQUESTS

7. If Defendants contend that the Exclusion of Gender-Confirming Care is supported by any governmental interest not encompassed in the Requests above, all Documents supporting that contention.

Exhibit
JM 12

SUPPLEMENTAL RESPONSE: Please see the attached budget and expenditure-related documents, Exhibits 60 - 85, Bates Numbers DHHRBMS002863 – DHHRBMS012160.

10. Documents sufficient to identify the circumstances in which orchiectomy, penectomy, vaginoplasty, hysterectomy, phalloplasty, mammoplasty, breast reconstruction surgery, and/or mastectomy are covered through the West Virginia Medicaid Program, including but not limited to Diagnostic Codes, Procedure Codes, contracts, health plans, clinical guidelines and/or criteria, medical necessity criteria, and pre/prior authorization requirements and procedures where applicable.

SUPPLEMENTAL RESPONSE: Please see Exhibits 10 – 26, Bates Numbers DHHRBMS001009 – DHHRBMS001112, previously produced. Additionally, please see Exhibits 50 – 57, Bates Numbers DHHRBMS002754 – DHHRBMS002784.

WILLIAM CROUCH,
CYNTHIA BEANE, and
WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES,

By counsel

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Roberta F. Green, Esquire (WVSB #6598)
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IN THE UNITED STATES DISTRICT COURT
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Defendants.

CERTIFICATE OF SERVICE

I, Kimberly M. Bandy, counsel for Defendants William Crouch, Cynthia Beane and West Virginia Department of Health and Human Resources, do hereby certify that on the 30th day of November, 2021, a true and exact copy of **DEFENDANTS' THIRD SUPPLEMENTAL RESPONSE TO PLAINTIFF'S FIRST SET OF REQUESTS FOR PRODUCTION TO DEFENDANTS WILLIAM CROUCH, CYNTHIA BEANE, AND WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES** was served on counsel via electronic means as follows:

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InterQual®

2021, Oct. 2021 Release CP:Procedures

Subset: Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11]

Requested Service: Hysterectomy +/- Salpingo-Oophorectomy or Salpingectomy for Endometriosis

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Endometriosis by laparoscopy

1. Treatment within last year, Choose all that apply:
   - ☐ A) GnRH agonist ≥ 8 weeks [12]
   - ☐ B) Hormone therapy ≥ 8 weeks [13]
   - ☐ C) Danazol ≥ 8 weeks [14]
   - ☐ D) Other clinical information (add comment)

> • If 1 or more options A, B or C selected and option D not selected, then go to question 2
> • No other options lead to the requested service

2. Continued symptoms after treatment [15]
   - ☐ A) Yes
   - ☐ B) No

> • If option Yes selected, then go to question 3
> • No other options lead to the requested service

EXHIBIT 10

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy +/- Salpingo-Oophorectomy or Salpingectomy for Endometriosis

Endometriosis by laparoscopy (continued...)

3. Choose all that apply:
   - ☐ A) Most recent cervical cytology normal or managed per guidelines [16]
   - ☐ B) Pregnancy excluded by negative HCG or HCG planned prior to procedure or sterilization by history or patient not sexually active by history [17, 18, 19, 20]
   - ☐ C) Other clinical information (add comment)

- If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here [21]
- No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

3:
Whether to perform prophylactic oophorectomy at the time of hysterectomy done for benign disease in premenopausal women may be considered. There are no published randomized studies to support conservation or prophylactic removal of the ovaries, although observational studies suggest that surgical menopause may increase cardiovascular and overall mortality risk (Orozco et al., The Cochrane database of systematic reviews 2014, 7: CD005638). Generally, bilateral salpingo-oophorectomy (BSO) is recommended for women with BRCA1 or BRCA2 mutations or Lynch syndrome, for postmenopausal women, and for women who have invasive endometrial or ovarian carcinoma (National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: breast and ovarian (Version 3.2019). 2019; National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: colorectal (Version 3.2019). 2019). BSO may also be considered in women who have chronic pelvic pain, pelvic inflammatory disease, or endometriosis, although the risks of surgery should be balanced against the anticipated benefits. Ovarian retention should be considered for premenopausal women who do not have a genetic predisposition to ovarian cancer. Ovarian epithelial carcinoma may originate in cells from the fallopian tube. Therefore, salpingectomy without oophorectomy may be considered in low-risk women who undergo hysterectomy or other pelvic surgery for benign disease, which reduces the risk of ovarian cancer without the development of surgical menopause (American College of Obstetrics and Gynecologists, Obstet Gynecol 2019, 133: e279-e84; Society of Gynecologic Oncology, SGO Clinical Practice Statement: Salpingectomy for Ovarian Cancer Prevention 2013).

4:
Although robotic-assisted hysterectomy is being done, there are few prospective studies comparing robotic assisted to laparoscopic surgery for treating benign disease (ACOG, Obstetrics and Gynecology Committee Opinion No. 628. 2015, 125: 760-7. Reaffirmed 2017; Yu et al., Journal of surgical oncology 2013, 107: 653-8). A Cochrane review, however, demonstrated that robotic-assisted gynecologic surgery required more intraoperative time but reduced hospital stay when compared to laparoscopic surgery. There is no clear evidence to determine which surgery has the lowest complication rate (Liu et al., The Cochrane database of systematic reviews 2014, 12: CD011422). Robotic-assisted surgery can be performed as an outpatient surgery in some patients (Lawrie et al., Cochrane Database Syst Rev 2019, 4: Cd011422).

5:
Total laparoscopic hysterectomy (TLH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are then secured by the endoscopic route. The fundus is then divided and removed through the abdominal wall incisions.

6:
Vaginal hysterectomy offers many advantages to the abdominal or laparoscopic approach including no abdominal incision, less pain, and quicker recovery; if technically feasible, it is the preferred surgical route (American College of Obstetricians and Gynecologists (ACOG), Obstet Gynecol 2017, 129: e155-e9; Sesti et al., Archives of Gynecology and Obstetrics 2014, 290: 485-91). The vaginal technique, however, can be limited in its ability to treat ovarian pathology in large uteri. The preoperative use of GnRH agonists may help shrink large uteri so that a vaginal hysterectomy can be performed (Elzaher et al., European Journal of Obstetrics, Gynecology, and Reproductive Biology 2013, 169: 326-30). Vaginal hysterectomy may be difficult to perform in nulliparous women, obese women, and women with a history of cesarean delivery.

7:
These criteria include the following procedures:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

8:
Laparoscopically assisted vaginal hysterectomy (LAVH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are not secured by the endoscopic route. A vaginal hysterectomy is then performed.

9:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

10:
For cervical cancer stage I-IIA and endometrial cancer stage II, see the "Hysterectomy, Radical" criteria subset.

11:
Supracervical hysterectomy (subtotal hysterectomy) performed as an open or laparoscopic procedure has been thought to preserve sexual, bladder, and bowel function by minimizing disruption of the pelvic floor support and neurovascular supply when compared with total hysterectomy. However, there is inconsistent evidence to show there is an improvement or significant difference in surgical complications, incontinence rate, bladder function, or sexual function when subtotal hysterectomy is compared to total hysterectomy (Lethaby et al., Cochrane Database Syst Rev 2012, 4: CD004993). One 5-year follow-up study of a randomized controlled trial, however, did show higher rates of urinary incontinence and vaginal bleeding in women who had a supracervical hysterectomy compared with those who had a total hysterectomy (Andersen et al., BJOG: An International Journal of Obstetrics and Gynaecology 2015, 122: 851-7). Disadvantages of supracervical hysterectomy include cervical stump complications (e.g., bleeding, pain) and the small risk of developing cervical cancer in the cervical stump (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013). Supracervical hysterectomy may not be appropriate in women who have gynecological cancers, endometrial hyperplasia, or cervical dysplasia (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013).

12:
The GnRH agonists include leuprolide, nafarelin, and goserelin. These compounds mimic the action of GnRH and, thereby, suppress the hormones produced by the ovary that stimulate endometrial growth.

13:
Medical therapy to treat symptoms of endometriosis may include combined contraceptive or progestin alone; their use is considered a first-line option (Brown and Farquhar, The Cochrane database of systematic reviews 2014, 3: CD009590). Depot medroxyprogesterone acetate, the progestin contraceptive implant, and the levonorgestrel intra-uterine system may also improve pain due to endometriosis (ACOG, Obstetrics and gynecology Practice Bulletin No. 110. 2010, 115: 206-218. Reaffirmed 2018).

14:
If symptoms do not respond to an oral contraceptive pill or GnRH agonist, then treatment with danazol or a progestin (e.g., depot medroxyprogesterone) is appropriate (Brown and Farquhar, Cochrane Database Syst Rev 2014: Cd009590).

15:
Symptoms of endometriosis include chronic recurrent pelvic pain, dysmenorrhea, infertility, and dyspareunia.

16:
Cervical cytology should be evaluated according to current screening protocols. Screening intervals and tests used (cervical cytology alone, high-risk human papillomavirus [hrHPV] testing alone, hrHPV and cytology together [co-testing]) will vary based on patient's age and risk factors. If the most recent cervical cytology is documented as normal, no further testing is needed. Any abnormalities detected during cervical cancer screening should be managed according to current guidelines. Management may include repeat testing, observation, surveillance, biopsy, ablation, or excisional treatment based on the identified level of risk for each patient (Redman et al., Eur J Obstet Gynecol Reprod Biol 2021, 256: 57-62; Perkins et al., J Low Genit Tract Dis 2020, 24: 102-31; US Preventative Services Task Force et al., JAMA 2018, 320: 674-86; Wentzensen et al., J Low Genit Tract Dis 2017, 21: 216-22).

17:
Pregnancy and related complications (e.g., ectopic pregnancy, incomplete abortion, inevitable abortion) must be excluded before performing this procedure.

18:
Pregnancy testing can be performed by measurement of either a serum or urine HCG and may be documented in the medical record by either the PCP, a gynecologist, or a surgeon.

19:
The documentation should include a history of sterilization (i.e., tubal ligation) without a subsequent pregnancy. These criteria do not include sterilization of a partner or alternate birth control methods (e.g., oral contraceptive pill use, intrauterine device insertion).

20:
Patients have varying definitions of sexual activity (e.g., number of partners, timing of most recent episode, frequency of sexual activity). Unless the provider can confirm on examination that the patient has never had sexual intercourse, whether a patient is sexually active or not is a matter of clinical judgment.

21:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-oophorectomy (BSO) - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-oophorectomy (BSO) - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-oophorectomy (BSO) - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/-Bilateral Salpingo-oophorectomy (BSO) - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-oophorectomy (BSO) - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-oophorectomy (BSO) - Due to variations in practice, this procedure can

be performed in the inpatient or outpatient setting

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy +/- Salpingo-Oophorectomy or Salpingectomy for Endometriosis

ICD-10-CM (circle all that apply): C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C79.82, D06.0, D06.1, D06.7, D06.9, D25.0, D25.1, D25.2, D25.9, N70.01, N70.02, N70.03, N70.11, N70.12, N70.13, N70.91, N70.92, N70.93, N71.1, N71.9, N72, N73.1, N73.4, N73.8, N73.9, N80.0, N80.1, N80.2, N80.3, N80.4, N80.5, N80.6, N80.8, N80.9, N81.2, N81.3, N81.4, N85.00, N85.01, N85.02, N87.0, N87.1, N87.9, N92.1, N92.4, N92.5, N93.0, N93.1, N93.8, N93.9, N95.0, O01.0, O01.1, O01.9, O72.0, O72.1, O72.2, O72.3, R10.10, R10.11, R10.12, R10.13, R10.2, R10.30, R10.31, R10.32, R10.33, R10.811, R10.812, R10.813, R10.814, R10.815, R10.816, R10.817, R10.819, R10.821, R10.822, R10.823, R10.824, R10.825, R10.826, R10.827, R10.829, R10.83, R10.84, R10.9, R19.00, R19.01, R19.02, R19.03, R19.04, R19.05, R19.06, R19.07, R19.09, R93.5, Z14.8, Z15.01, Z15.02, Z15.04, Z15.09, Z15.89, Other _____

ICD-10-PCS (circle all that apply): 0UT20ZZ, 0UT24ZZ, 0UT27ZZ, 0UT28ZZ, 0UT2FZZ, 0UT70ZZ, 0UT74ZZ, 0UT77ZZ, 0UT78ZZ, 0UT7FZZ, 0UT90ZL, 0UT90ZZ, 0UT94ZL, 0UT94ZZ, 0UT97ZL, 0UT97ZZ, 0UT98ZL, 0UT98ZZ, 0UT9FZL, 0UT9FZZ, 0UTC0ZZ, 0UTC4ZZ, 0UTC7ZZ, 0UTC8ZZ, Other _____

CPT® (circle all that apply): 58150, 58152, 58180, 58260, 58262, 58263, 58290, 58291, 58292, 58541, 58542, 58543, 58544, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573, 58575, Other _____

InterQual®

2021, Oct. 2021 Release CP:Procedures

Subset: Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11]

Requested Service: Hysterectomy + BSO for BRCA gene mutation

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. BRCA1 or BRCA2 gene mutation by genetic testing

There are no questions for the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

DHHRBMS001016

Notes:

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3:
Whether to perform prophylactic oophorectomy at the time of hysterectomy done for benign disease in premenopausal women may be considered. There are no published randomized studies to support conservation or prophylactic removal of the ovaries, although observational studies suggest that surgical menopause may increase cardiovascular and overall mortality risk (Orozco et al., The Cochrane database of systematic reviews 2014, 7: CD005638). Generally, bilateral salpingo-oophorectomy (BSO) is recommended for women with BRCA1 or BRCA2 mutations or Lynch syndrome, for postmenopausal women, and for women who have invasive endometrial or ovarian carcinoma (National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: breast and ovarian (Version 3.2019). 2019; National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: colorectal (Version 3.2019). 2019). BSO may also be considered in women who have chronic pelvic pain, pelvic inflammatory disease, or endometriosis, although the risks of surgery should be balanced against the anticipated benefits. Ovarian retention should be considered for premenopausal women who do not have a genetic predisposition to ovarian cancer. Ovarian epithelial carcinoma may originate in cells from the fallopian tube. Therefore, salpingectomy without oophorectomy may be considered in low-risk women who undergo hysterectomy or other pelvic surgery for benign disease, which reduces the risk of ovarian cancer without the development of surgical menopause (American College of Obstetrics and Gynecologists, Obstet Gynecol 2019, 133: e279-e84; Society of Gynecologic Oncology, SGO Clinical Practice Statement: Salpingectomy for Ovarian Cancer Prevention 2013).

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Although robotic-assisted hysterectomy is being done, there are few prospective studies comparing robotic assisted to laparoscopic surgery for treating benign disease (ACOG, Obstetrics and Gynecology Committee Opinion No. 628. 2015, 125: 760-7. Reaffirmed 2017; Yu et al., Journal of surgical oncology 2013, 107: 653-8). A Cochrane review, however, demonstrated that robotic-assisted gynecologic surgery required more intraoperative time but reduced hospital stay when compared to laparoscopic surgery. There is no clear evidence to determine which surgery has the lowest complication rate (Liu et al., The Cochrane database of systematic reviews 2014, 12: CD011422). Robotic-assisted surgery can be performed as an outpatient surgery in some patients (Lawrie et al., Cochrane Database Syst Rev 2019, 4: Cd011422).

5:
Total laparoscopic hysterectomy (TLH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are then secured by the endoscopic route. The fundus is then divided and removed through the abdominal wall incisions.

6:
Vaginal hysterectomy offers many advantages to the abdominal or laparoscopic approach including no abdominal incision, less pain, and quicker recovery; if technically feasible, it is the preferred surgical route (American College of Obstetricians and Gynecologists (ACOG), Obstet Gynecol 2017, 129: e155-e9; Sesti et al., Archives of Gynecology and Obstetrics 2014, 290: 485-91). The vaginal technique, however, can be limited in its ability to treat ovarian pathology in large uteri. The preoperative use of GnRH agonists may help shrink large uteri so that a vaginal hysterectomy can be performed (Elzaher et al., European Journal of Obstetrics, Gynecology, and Reproductive Biology 2013, 169: 326-30). Vaginal hysterectomy may be difficult to perform in nulliparous women, obese women, and women with a history of cesarean delivery.

7:
These criteria include the following procedures:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

8:
Laparoscopically assisted vaginal hysterectomy (LAVH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are not secured by the endoscopic route. A vaginal hysterectomy is then performed.

9:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

10:
For cervical cancer stage I-IIA and endometrial cancer stage II, see the "Hysterectomy, Radical" criteria subset.

11:
Supracervical hysterectomy (subtotal hysterectomy) performed as an open or laparoscopic procedure has been thought to preserve sexual, bladder, and bowel function by minimizing disruption of the pelvic floor support and neurovascular supply when compared with total hysterectomy. However, there is inconsistent evidence to show there is an improvement or significant difference in surgical complications, incontinence rate, bladder function, or sexual function when subtotal hysterectomy is compared to total hysterectomy (Lethaby et al., Cochrane Database Syst Rev 2012, 4: CD004993). One 5-year follow-up study of a randomized controlled trial, however, did show higher rates of urinary incontinence and vaginal bleeding in women who had a supracervical hysterectomy compared with those who had a total hysterectomy (Andersen et al., BJOG: An International Journal of Obstetrics and Gynaecology 2015, 122: 851-7). Disadvantages of supracervical hysterectomy include cervical stump complications (e.g., bleeding, pain) and the small risk of developing cervical cancer in the cervical stump (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013). Supracervical hysterectomy may not be appropriate in women who have gynecological cancers, endometrial hyperplasia, or cervical dysplasia (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013).

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy + BSO for BRCA gene mutation

ICD-10-CM (circle all that apply): C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C79.82, D06.0, D06.1, D06.7, D06.9, D25.0, D25.1, D25.2, D25.9, N70.01, N70.02, N70.03, N70.11, N70.12, N70.13, N70.91, N70.92, N70.93, N71.1, N71.9, N72, N73.1, N73.4, N73.8, N73.9, N80.0, N80.1, N80.2, N80.3, N80.4, N80.5, N80.6, N80.8, N80.9, N81.2, N81.3, N81.4, N85.00, N85.01, N85.02, N87.0, N87.1, N87.9, N92.1, N92.4, N92.5, N93.0, N93.1, N93.8, N93.9, N95.0, O01.0, O01.1, O01.9, O72.0, O72.1, O72.2, O72.3, R10.10, R10.11, R10.12, R10.13, R10.2, R10.30, R10.31, R10.32, R10.33, R10.811, R10.812, R10.813, R10.814, R10.815, R10.816, R10.817, R10.819, R10.821, R10.822, R10.823, R10.824, R10.825, R10.826, R10.827, R10.829, R10.83, R10.84, R10.9, R19.00, R19.01, R19.02, R19.03, R19.04, R19.05, R19.06, R19.07, R19.09, R93.5, Z14.8, Z15.01, Z15.02, Z15.04, Z15.09, Z15.89, Other _____

ICD-10-PCS (circle all that apply): 0UT20ZZ, 0UT24ZZ, 0UT27ZZ, 0UT28ZZ, 0UT2FZZ, 0UT70ZZ, 0UT74ZZ, 0UT77ZZ, 0UT78ZZ, 0UT7FZZ, 0UT90ZL, 0UT90ZZ, 0UT94ZL, 0UT94ZZ, 0UT97ZL, 0UT97ZZ, 0UT98ZL, 0UT98ZZ, 0UT9FZL, 0UT9FZZ, 0UTC0ZZ, 0UTC4ZZ, 0UTC7ZZ, 0UTC8ZZ, Other _____

CPT® (circle all that apply): 58150, 58152, 58180, 58262, 58291, 58542, 58544, 58552, 58554, 58571, 58573, 58575, Other _____

InterQual®

2021, Oct. 2021 Release CP:Procedures

Subset: Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy (1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11)

Requested Service: Hysterectomy +/- BSO or Bilateral Salpingectomy for Endocervical adenocarcinoma in situ

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:	Date:	
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Endocervical adenocarcinoma in situ by biopsy

There are no questions for the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

DHHRBMS001021

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

3:
Whether to perform prophylactic oophorectomy at the time of hysterectomy done for benign disease in premenopausal women may be considered. There are no published randomized studies to support conservation or prophylactic removal of the ovaries, although observational studies suggest that surgical menopause may increase cardiovascular and overall mortality risk (Orozco et al., The Cochrane database of systematic reviews 2014, 7: CD005638). Generally, bilateral salpingo-oophorectomy (BSO) is recommended for women with BRCA1 or BRCA2 mutations or Lynch syndrome, for postmenopausal women, and for women who have invasive endometrial or ovarian carcinoma (National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: breast and ovarian (Version 3.2019). 2019; National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: colorectal (Version 3.2019). 2019). BSO may also be considered in women who have chronic pelvic pain, pelvic inflammatory disease, or endometriosis, although the risks of surgery should be balanced against the anticipated benefits. Ovarian retention should be considered for premenopausal women who do not have a genetic predisposition to ovarian cancer. Ovarian epithelial carcinoma may originate in cells from the fallopian tube. Therefore, salpingectomy without oophorectomy may be considered in low-risk women who undergo hysterectomy or other pelvic surgery for benign disease, which reduces the risk of ovarian cancer without the development of surgical menopause (American College of Obstetrics and Gynecologists, Obstet Gynecol 2019, 133: e279-e84; Society of Gynecologic Oncology, SGO Clinical Practice Statement: Salpingectomy for Ovarian Cancer Prevention 2013).

4:
Although robotic-assisted hysterectomy is being done, there are few prospective studies comparing robotic assisted to laparoscopic surgery for treating benign disease (ACOG, Obstetrics and Gynecology Committee Opinion No. 628. 2015, 125: 760-7. Reaffirmed 2017; Yu et al., Journal of surgical oncology 2013, 107: 653-8). A Cochrane review, however, demonstrated that robotic-assisted gynecologic surgery required more intraoperative time but reduced hospital stay when compared to laparoscopic surgery. There is no clear evidence to determine which surgery has the lowest complication rate (Liu et al., The Cochrane database of systematic reviews 2014, 12: CD011422). Robotic-assisted surgery can be performed as an outpatient surgery in some patients (Lawrie et al., Cochrane Database Syst Rev 2019, 4: Cd011422).

5:
Total laparoscopic hysterectomy (TLH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are then secured by the endoscopic route. The fundus is then divided and removed through the abdominal wall incisions.

6:
Vaginal hysterectomy offers many advantages to the abdominal or laparoscopic approach including no abdominal incision, less pain, and quicker recovery; if technically feasible, it is the preferred surgical route (American College of Obstetricians and Gynecologists (ACOG), Obstet Gynecol 2017, 129: e155-e9; Sesti et al., Archives of Gynecology and Obstetrics 2014, 290: 485-91). The vaginal technique, however, can be limited in its ability to treat ovarian pathology in large uteri. The preoperative use of GnRH agonists may help shrink large uteri so that a vaginal hysterectomy can be performed (Elzaher et al., European Journal of Obstetrics, Gynecology, and Reproductive Biology 2013, 169: 326-30). Vaginal hysterectomy may be difficult to perform in nulliparous women, obese women, and women with a history of cesarean delivery.

7:
These criteria include the following procedures:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

8:
Laparoscopically assisted vaginal hysterectomy (LAVH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are not secured by the endoscopic route. A vaginal hysterectomy is then performed.

9:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

10:
For cervical cancer stage I-IIA and endometrial cancer stage II, see the "Hysterectomy, Radical" criteria subset.

11:
Supracervical hysterectomy (subtotal hysterectomy) performed as an open or laparoscopic procedure has been thought to preserve sexual, bladder, and bowel function by minimizing disruption of the pelvic floor support and neurovascular supply when compared with total hysterectomy. However, there is inconsistent evidence to show there is an improvement or significant difference in surgical complications, incontinence rate, bladder function, or sexual function when subtotal hysterectomy is compared to total hysterectomy (Lethaby et al., Cochrane Database Syst Rev 2012, 4: CD004993). One 5-year follow-up study of a randomized controlled trial, however, did show higher rates of urinary incontinence and vaginal bleeding in women who had a supracervical hysterectomy compared with those who had a total hysterectomy (Andersen et al., BJOG: An International Journal of Obstetrics and Gynaecology 2015, 122: 851-7). Disadvantages of supracervical hysterectomy include cervical stump complications (e.g., bleeding, pain) and the small risk of developing cervical cancer in the cervical stump (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013). Supracervical hysterectomy may not be appropriate in women who have gynecological cancers, endometrial hyperplasia, or cervical dysplasia (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013).

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy +/- BSO or Bilateral Salpingectomy for Endocervical adenocarcinoma in situ

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ICD-10-CM (circle all that apply): C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C79.82, D06.0, D06.1, D06.7, D06.9, D25.0, D25.1, D25.2, D25.9, N70.01, N70.02, N70.03, N70.11, N70.12, N70.13, N70.91, N70.92, N70.93, N71.1, N71.9, N72, N73.1, N73.4, N73.8, N73.9, N80.0, N80.1, N80.2, N80.3, N80.4, N80.5, N80.6, N80.8, N80.9, N81.2, N81.3, N81.4, N85.00, N85.01, N85.02, N87.0, N87.1, N87.9, N92.1, N92.4, N92.5, N93.0, N93.1, N93.8, N93.9, N95.0, O01.0, O01.1, O01.9, O72.0, O72.1, O72.2, O72.3, R10.10, R10.11, R10.12, R10.13, R10.2, R10.30, R10.31, R10.32, R10.33, R10.811, R10.812, R10.813, R10.814, R10.815, R10.816, R10.817, R10.819, R10.821, R10.822, R10.823, R10.824, R10.825, R10.826, R10.827, R10.829, R10.83, R10.84, R10.9, R19.00, R19.01, R19.02, R19.03, R19.04, R19.05, R19.06, R19.07, R19.09, R93.5, Z14.8, Z15.01, Z15.02, Z15.04, Z15.09, Z15.89, Other _____

ICD-10-PCS (circle all that apply): 0UT20ZZ, 0UT24ZZ, 0UT27ZZ, 0UT28ZZ, 0UT2FZZ, 0UT70ZZ, 0UT74ZZ, 0UT77ZZ, 0UT78ZZ, 0UT7FZZ, 0UT90ZZ, 0UT94ZZ, 0UT97ZZ, 0UT98ZZ, 0UT9FZZ, 0UTC0ZZ, 0UTC4ZZ, 0UTC7ZZ, 0UTC8ZZ, Other _____

CPT® (circle all that apply): 58150, 58152, 58260, 58262, 58263, 58290, 58291, 58292, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573, 58575, Other _____

InterQual®

2021, Oct. 2021 Release CP:Procedures

Subset: Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy (1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11)

Requested Service: Hysterectomy + BSO for Endometrial cancer

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Stage I or IA or IB endometrial cancer by pathology

There are no questions for the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

DHHRBMS001026

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy + BSO for Endometrial cancer

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

3:
Whether to perform prophylactic oophorectomy at the time of hysterectomy done for benign disease in premenopausal women may be considered. There are no published randomized studies to support conservation or prophylactic removal of the ovaries, although observational studies suggest that surgical menopause may increase cardiovascular and overall mortality risk (Orozco et al., The Cochrane database of systematic reviews 2014, 7: CD005638). Generally, bilateral salpingo-oophorectomy (BSO) is recommended for women with BRCA1 or BRCA2 mutations or Lynch syndrome, for postmenopausal women, and for women who have invasive endometrial or ovarian carcinoma (National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: breast and ovarian (Version 3.2019). 2019; National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: colorectal (Version 3.2019). 2019). BSO may also be considered in women who have chronic pelvic pain, pelvic inflammatory disease, or endometriosis, although the risks of surgery should be balanced against the anticipated benefits. Ovarian retention should be considered for premenopausal women who do not have a genetic predisposition to ovarian cancer. Ovarian epithelial carcinoma may originate in cells from the fallopian tube. Therefore, salpingectomy without oophorectomy may be considered in low-risk women who undergo hysterectomy or other pelvic surgery for benign disease, which reduces the risk of ovarian cancer without the development of surgical menopause (American College of Obstetrics and Gynecologists, Obstet Gynecol 2019, 133: e279-e84; Society of Gynecologic Oncology, SGO Clinical Practice Statement: Salpingectomy for Ovarian Cancer Prevention 2013).

4:
Although robotic-assisted hysterectomy is being done, there are few prospective studies comparing robotic assisted to laparoscopic surgery for treating benign disease (ACOG, Obstetrics and Gynecology Committee Opinion No. 628. 2015, 125: 760-7. Reaffirmed 2017; Yu et al., Journal of surgical oncology 2013, 107: 653-8). A Cochrane review, however, demonstrated that robotic-assisted gynecologic surgery required more intraoperative time but reduced hospital stay when compared to laparoscopic surgery. There is no clear evidence to determine which surgery has the lowest complication rate (Liu et al., The Cochrane database of systematic reviews 2014, 12: CD011422). Robotic-assisted surgery can be performed as an outpatient surgery in some patients (Lawrie et al., Cochrane Database Syst Rev 2019, 4: Cd011422).

5:
Total laparoscopic hysterectomy (TLH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are then secured by the endoscopic route. The fundus is then divided and removed through the abdominal wall incisions.

6:
Vaginal hysterectomy offers many advantages to the abdominal or laparoscopic approach including no abdominal incision, less pain, and quicker recovery; if technically feasible, it is the preferred surgical route (American College of Obstetricians and Gynecologists (ACOG), Obstet Gynecol 2017, 129: e155-e9; Sesti et al., Archives of Gynecology and Obstetrics 2014, 290: 485-91). The vaginal technique, however, can be limited in its ability to treat ovarian pathology in large uteri. The preoperative use of GnRH agonists may help shrink large uteri so that a vaginal hysterectomy can be performed (Elzaher et al., European Journal of Obstetrics, Gynecology, and Reproductive Biology 2013, 169: 326-30). Vaginal hysterectomy may be difficult to perform in nulliparous women, obese women, and women with a history of cesarean delivery.

7:
These criteria include the following procedures:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

8:
Laparoscopically assisted vaginal hysterectomy (LAVH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are not secured by the endoscopic route. A vaginal hysterectomy is then performed.

9:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

10:
For cervical cancer stage I-IIA and endometrial cancer stage II, see the "Hysterectomy, Radical" criteria subset.

11:
Supracervical hysterectomy (subtotal hysterectomy) performed as an open or laparoscopic procedure has been thought to preserve sexual, bladder, and bowel function by minimizing disruption of the pelvic floor support and neurovascular supply when compared with total hysterectomy. However, there is inconsistent evidence to show there is an improvement or significant difference in surgical complications, incontinence rate, bladder function, or sexual function when subtotal hysterectomy is compared to total hysterectomy (Lethaby et al., Cochrane Database Syst Rev 2012, 4: CD004993). One 5-year follow-up study of a randomized controlled trial, however, did show higher rates of urinary incontinence and vaginal bleeding in women who had a supracervical hysterectomy compared with those who had a total hysterectomy (Andersen et al., BJOG: An International Journal of Obstetrics and Gynaecology 2015, 122: 851-7). Disadvantages of supracervical hysterectomy include cervical stump complications (e.g., bleeding, pain) and the small risk of developing cervical cancer in the cervical stump (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013). Supracervical hysterectomy may not be appropriate in women who have gynecological cancers, endometrial hyperplasia, or cervical dysplasia (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013).

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy + BSO for Endometrial cancer

ICD-10-CM (circle all that apply): C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C79.82, D06.0, D06.1, D06.7, D06.9, D25.0, D25.1, D25.2, D25.9, N70.01, N70.02, N70.03, N70.11, N70.12, N70.13, N70.91, N70.92, N70.93, N71.1, N71.9, N72, N73.1, N73.4, N73.8, N73.9, N80.0, N80.1, N80.2, N80.3, N80.4, N80.5, N80.6, N80.8, N80.9, N81.2, N81.3, N81.4, N85.00, N85.01, N85.02, N87.0, N87.1, N87.9, N92.1, N92.4, N92.5, N93.0, N93.1, N93.8, N93.9, N95.0, O01.0, O01.1, O01.9, O72.0, O72.1, O72.2, O72.3, R10.10, R10.11, R10.12, R10.13, R10.2, R10.30, R10.31, R10.32, R10.33, R10.811, R10.812, R10.813, R10.814, R10.815, R10.816, R10.817, R10.819, R10.821, R10.822, R10.823, R10.824, R10.825, R10.826, R10.827, R10.829, R10.83, R10.84, R10.9, R19.00, R19.01, R19.02, R19.03, R19.04, R19.05, R19.06, R19.07, R19.09, R93.5, Z14.8, Z15.01, Z15.02, Z15.04, Z15.09, Z15.89, Other _____

ICD-10-PCS (circle all that apply): 0UT20ZZ, 0UT24ZZ, 0UT28ZZ, 0UT2FZZ, 0UT70ZZ, 0UT74ZZ, 0UT78ZZ, 0UT7FZZ, 0UT90ZZ, 0UT94ZZ, 0UT98ZZ, 0UT9FZZ, 0UTC0ZZ, 0UTC4ZZ, 0UTC8ZZ, Other _____

CPT® (circle all that apply): 58150, 58152, 58552, 58554, 58571, 58573, 58575, Other _____

InterQual®

2021, Oct. 2021 Release CP:Procedures

Subset: Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11]

Requested Service: Hysterectomy + BSO for Endometrial hyperplasia (postmenopausal)

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Endometrial hyperplasia with cellular atypia by biopsy or dilatation and curettage (D & C)

1. Choose one:
   - ☐ A) Premenopausal woman
   - ☐ B) Postmenopausal woman [12]
   - ☐ C) Other clinical information (add comment)

> • If option B selected, then the rule is satisfied; you may stop here [13]
> • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

DHHRBMS001031

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

3:
Whether to perform prophylactic oophorectomy at the time of hysterectomy done for benign disease in premenopausal women may be considered. There are no published randomized studies to support conservation or prophylactic removal of the ovaries, although observational studies suggest that surgical menopause may increase cardiovascular and overall mortality risk (Orozco et al., The Cochrane database of systematic reviews 2014, 7: CD005638). Generally, bilateral salpingo-oophorectomy (BSO) is recommended for women with BRCA1 or BRCA2 mutations or Lynch syndrome, for postmenopausal women, and for women who have invasive endometrial or ovarian carcinoma (National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: breast and ovarian (Version 3.2019). 2019; National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: colorectal (Version 3.2019). 2019). BSO may also be considered in women who have chronic pelvic pain, pelvic inflammatory disease, or endometriosis, although the risks of surgery should be balanced against the anticipated benefits. Ovarian retention should be considered for premenopausal women who do not have a genetic predisposition to ovarian cancer. Ovarian epithelial carcinoma may originate in cells from the fallopian tube. Therefore, salpingectomy without oophorectomy may be considered in low-risk women who undergo hysterectomy or other pelvic surgery for benign disease, which reduces the risk of ovarian cancer without the development of surgical menopause (American College of Obstetrics and Gynecologists, Obstet Gynecol 2019, 133: e279-e84; Society of Gynecologic Oncology, SGO Clinical Practice Statement: Salpingectomy for Ovarian Cancer Prevention 2013).

4:
Although robotic-assisted hysterectomy is being done, there are few prospective studies comparing robotic assisted to laparoscopic surgery for treating benign disease (ACOG, Obstetrics and Gynecology Committee Opinion No. 628. 2015, 125: 760-7. Reaffirmed 2017; Yu et al., Journal of surgical oncology 2013, 107: 653-8). A Cochrane review, however, demonstrated that robotic-assisted gynecologic surgery required more intraoperative time but reduced hospital stay when compared to laparoscopic surgery. There is no clear evidence to determine which surgery has the lowest complication rate (Liu et al., The Cochrane database of systematic reviews 2014, 12: CD011422). Robotic-assisted surgery can be performed as an outpatient surgery in some patients (Lawrie et al., Cochrane Database Syst Rev 2019, 4: Cd011422).

5:
Total laparoscopic hysterectomy (TLH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are then secured by the endoscopic route. The fundus is then divided and removed through the abdominal wall incisions.

6:
Vaginal hysterectomy offers many advantages to the abdominal or laparoscopic approach including no abdominal incision, less pain, and quicker recovery; if technically feasible, it is the preferred surgical route (American College of Obstetricians and Gynecologists (ACOG), Obstet Gynecol 2017, 129: e155-e9; Sesti et al., Archives of Gynecology and Obstetrics 2014, 290: 485-91). The vaginal technique, however, can be limited in its ability to treat ovarian pathology in large uteri. The preoperative use of GnRH agonists may help shrink large uteri so that a vaginal hysterectomy can be performed (Elzaher et al., European Journal of Obstetrics, Gynecology, and Reproductive Biology 2013, 169: 326-30). Vaginal hysterectomy may be difficult to perform in nulliparous women, obese women, and women with a history of cesarean delivery.

7:
These criteria include the following procedures:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

8:
Laparoscopically assisted vaginal hysterectomy (LAVH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are not secured by the endoscopic route. A vaginal hysterectomy is then performed.

9:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

10:
For cervical cancer stage I-IIA and endometrial cancer stage II, see the "Hysterectomy, Radical" criteria subset.

11:
Supracervical hysterectomy (subtotal hysterectomy) performed as an open or laparoscopic procedure has been thought to preserve sexual, bladder, and bowel function by minimizing disruption of the pelvic floor support and neurovascular supply when compared with total hysterectomy. However, there is inconsistent evidence to show there is an improvement or significant difference in surgical complications, incontinence rate, bladder function, or sexual function when subtotal hysterectomy is compared to total hysterectomy (Lethaby et al., Cochrane Database Syst Rev 2012, 4: CD004993). One 5-year follow-up study of a randomized controlled trial, however, did show higher rates of urinary incontinence and vaginal bleeding in women who had a supracervical hysterectomy compared with those who had a total hysterectomy (Andersen et al., BJOG: An International Journal of Obstetrics and Gynaecology 2015, 122: 851-7). Disadvantages of supracervical hysterectomy include cervical stump complications (e.g., bleeding, pain) and the small risk of developing cervical cancer in the cervical stump (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013). Supracervical hysterectomy may not be appropriate in women who have gynecological cancers, endometrial hyperplasia, or cervical dysplasia (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013).

12:
Hysterectomy with removal of both ovaries and fallopian tubes is usually performed in postmenopausal women because the risk for the development of ovarian cancer is higher than for premenopausal women.

13:
I/O Setting:
Hysterectomy, Abdominal, Total + Bilateral Salpingo-Oophorectomy (BSO) - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) + Bilateral Salpingo-Oophorectomy (BSO) - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Total (TLH) + Bilateral Salpingo-Oophorectomy (BSO) - Outpatient
Hysterectomy, Vaginal + Bilateral Salpingo-Oophorectomy (BSO) - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy + BSO for Endometrial hyperplasia (postmenopausal)

ICD-10-CM (circle all that apply): C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C79.82, D06.0, D06.1, D06.7, D06.9, D25.0, D25.1, D25.2, D25.9, N70.01, N70.02, N70.03, N70.11, N70.12, N70.13, N70.91, N70.92, N70.93, N71.1, N71.9, N72, N73.1, N73.4, N73.8, N73.9, N80.0, N80.1, N80.2, N80.3, N80.4, N80.5, N80.6, N80.8, N80.9, N81.2, N81.3, N81.4, N85.00, N85.01, N85.02, N87.0, N87.1, N87.9, N92.1, N92.4, N92.5, N93.0, N93.1, N93.8, N93.9, N95.0, O01.0, O01.1, O01.9, O72.0, O72.1, O72.2, O72.3, R10.10, R10.11, R10.12, R10.13, R10.2, R10.30, R10.31, R10.32, R10.33, R10.811, R10.812, R10.813, R10.814, R10.815, R10.816, R10.817, R10.819, R10.821, R10.822, R10.823, R10.824, R10.825, R10.826, R10.827, R10.829, R10.83, R10.84, R10.9, R19.00, R19.01, R19.02, R19.03, R19.04, R19.05, R19.06, R19.07, R19.09, R93.5, Z14.8, Z15.01, Z15.02, Z15.04, Z15.09, Z15.89, Other _____

ICD-10-PCS (circle all that apply): 0UT20ZZ, 0UT24ZZ, 0UT27ZZ, 0UT28ZZ, 0UT2FZZ, 0UT70ZZ, 0UT74ZZ, 0UT77ZZ, 0UT78ZZ, 0UT7FZZ, 0UT90ZZ, 0UT94ZZ, 0UT97ZZ, 0UT98ZZ, 0UT9FZZ, 0UTC0ZZ, 0UTC4ZZ, 0UTC7ZZ, 0UTC8ZZ, Other _____

CPT® (circle all that apply): 58150, 58152, 58262, 58263, 58291, 58292, 58552, 58554, 58571, 58573, 58575, Other _____

InterQual®

2021, Oct. 2021 Release CP:Procedures

Subset: Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy (1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11)

Requested Service: Hysterectomy + BSO for Lynch II syndrome

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Lynch II syndrome

There are no questions for the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

DHHRBMS001036

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy + BSO for Lynch II syndrome

Notes:

1:
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2:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

3:
Whether to perform prophylactic oophorectomy at the time of hysterectomy done for benign disease in premenopausal women may be considered. There are no published randomized studies to support conservation or prophylactic removal of the ovaries, although observational studies suggest that surgical menopause may increase cardiovascular and overall mortality risk (Orozco et al., The Cochrane database of systematic reviews 2014, 7: CD005638). Generally, bilateral salpingo-oophorectomy (BSO) is recommended for women with BRCA1 or BRCA2 mutations or Lynch syndrome, for postmenopausal women, and for women who have invasive endometrial or ovarian carcinoma (National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: breast and ovarian (Version 3.2019). 2019; National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: colorectal (Version 3.2019). 2019). BSO may also be considered in women who have chronic pelvic pain, pelvic inflammatory disease, or endometriosis, although the risks of surgery should be balanced against the anticipated benefits. Ovarian retention should be considered for premenopausal women who do not have a genetic predisposition to ovarian cancer. Ovarian epithelial carcinoma may originate in cells from the fallopian tube. Therefore, salpingectomy without oophorectomy may be considered in low-risk women who undergo hysterectomy or other pelvic surgery for benign disease, which reduces the risk of ovarian cancer without the development of surgical menopause (American College of Obstetrics and Gynecologists, Obstet Gynecol 2019, 133: e279-e84; Society of Gynecologic Oncology, SGO Clinical Practice Statement: Salpingectomy for Ovarian Cancer Prevention 2013).

4:
Although robotic-assisted hysterectomy is being done, there are few prospective studies comparing robotic assisted to laparoscopic surgery for treating benign disease (ACOG, Obstetrics and Gynecology Committee Opinion No. 628. 2015, 125: 760-7. Reaffirmed 2017; Yu et al., Journal of surgical oncology 2013, 107: 653-8). A Cochrane review, however, demonstrated that robotic-assisted gynecologic surgery required more intraoperative time but reduced hospital stay when compared to laparoscopic surgery. There is no clear evidence to determine which surgery has the lowest complication rate (Liu et al., The Cochrane database of systematic reviews 2014, 12: CD011422). Robotic-assisted surgery can be performed as an outpatient surgery in some patients (Lawrie et al., Cochrane Database Syst Rev 2019, 4: Cd011422).

5:
Total laparoscopic hysterectomy (TLH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are then secured by the endoscopic route. The fundus is then divided and removed through the abdominal wall incisions.

6:
Vaginal hysterectomy offers many advantages to the abdominal or laparoscopic approach including no abdominal incision, less pain, and quicker recovery; if technically feasible, it is the preferred surgical route (American College of Obstetricians and Gynecologists (ACOG), Obstet Gynecol 2017, 129: e155-e9; Sesti et al., Archives of Gynecology and Obstetrics 2014, 290: 485-91). The vaginal technique, however, can be limited in its ability to treat ovarian pathology in large uteri. The preoperative use of GnRH agonists may help shrink large uteri so that a vaginal hysterectomy can be performed (Elzaher et al., European Journal of Obstetrics, Gynecology, and Reproductive Biology 2013, 169: 326-30). Vaginal hysterectomy may be difficult to perform in nulliparous women, obese women, and women with a history of cesarean delivery.

7:
These criteria include the following procedures:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

8:
Laparoscopically assisted vaginal hysterectomy (LAVH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are not secured by the endoscopic route. A vaginal hysterectomy is then performed.

9:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

10:
For cervical cancer stage I-IIA and endometrial cancer stage II, see the "Hysterectomy, Radical" criteria subset.

11:
Supracervical hysterectomy (subtotal hysterectomy) performed as an open or laparoscopic procedure has been thought to preserve sexual, bladder, and bowel function by minimizing disruption of the pelvic floor support and neurovascular supply when compared with total hysterectomy. However, there is inconsistent evidence to show there is an improvement or significant difference in surgical complications, incontinence rate, bladder function, or sexual function when subtotal hysterectomy is compared to total hysterectomy (Lethaby et al., Cochrane Database Syst Rev 2012, 4: CD004993). One 5-year follow-up study of a randomized controlled trial, however, did show higher rates of urinary incontinence and vaginal bleeding in women who had a supracervical hysterectomy compared with those who had a total hysterectomy (Andersen et al., BJOG: An International Journal of Obstetrics and Gynaecology 2015, 122: 851-7). Disadvantages of supracervical hysterectomy include cervical stump complications (e.g., bleeding, pain) and the small risk of developing cervical cancer in the cervical stump (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013). Supracervical hysterectomy may not be appropriate in women who have gynecological cancers, endometrial hyperplasia, or cervical dysplasia (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013).

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy + BSO for Lynch II syndrome

ICD-10-CM (circle all that apply): C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C79.82, D06.0, D06.1, D06.7, D06.9, D25.0, D25.1, D25.2, D25.9, N70.01, N70.02, N70.03, N70.11, N70.12, N70.13, N70.91, N70.92, N70.93, N71.1, N71.9, N72, N73.1, N73.4, N73.8, N73.9, N80.0, N80.1, N80.2, N80.3, N80.4, N80.5, N80.6, N80.8, N80.9, N81.2, N81.3, N81.4, N85.00, N85.01, N85.02, N87.0, N87.1, N87.9, N92.1, N92.4, N92.5, N93.0, N93.1, N93.8, N93.9, N95.0, O01.0, O01.1, O01.9, O72.0, O72.1, O72.2, O72.3, R10.10, R10.11, R10.12, R10.13, R10.2, R10.30, R10.31, R10.32, R10.33, R10.811, R10.812, R10.813, R10.814, R10.815, R10.816, R10.817, R10.819, R10.821, R10.822, R10.823, R10.824, R10.825, R10.826, R10.827, R10.829, R10.83, R10.84, R10.9, R19.00, R19.01, R19.02, R19.03, R19.04, R19.05, R19.06, R19.07, R19.09, R93.5, Z14.8, Z15.01, Z15.02, Z15.04, Z15.09, Z15.89, Other _____

ICD-10-PCS (circle all that apply): 0UT20ZZ, 0UT24ZZ, 0UT70ZZ, 0UT74ZZ, 0UT90ZL, 0UT90ZZ, 0UT94ZL, 0UT94ZZ, 0UTC0ZZ, 0UTC4ZZ, Other _____

CPT® (circle all that apply): 58150, 58152, 58571, 58573, 58575, Other _____

InterQual®

2021, Oct. 2021 Release CP:Procedures

Subset: Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11]

Requested Service: Hysterectomy + BSO for Suspected Ovarian or Tubal cancer

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Choose one of the following options and continue to the appropriate section

- ☐ 10. Suspected ovarian cancer by imaging
- ☐ 20. Suspected tubal cancer by imaging

☐ 10. Suspected ovarian cancer by imaging

There are no questions for the requested service

☐ 20. Suspected tubal cancer by imaging

There are no questions for the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

DHHRBMS001041

Notes:

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2:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

3:
Whether to perform prophylactic oophorectomy at the time of hysterectomy done for benign disease in premenopausal women may be considered. There are no published randomized studies to support conservation or prophylactic removal of the ovaries, although observational studies suggest that surgical menopause may increase cardiovascular and overall mortality risk (Orozco et al., The Cochrane database of systematic reviews 2014, 7: CD005638). Generally, bilateral salpingo-oophorectomy (BSO) is recommended for women with BRCA1 or BRCA2 mutations or Lynch syndrome, for postmenopausal women, and for women who have invasive endometrial or ovarian carcinoma (National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: breast and ovarian (Version 3.2019). 2019; National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: colorectal (Version 3.2019). 2019). BSO may also be considered in women who have chronic pelvic pain, pelvic inflammatory disease, or endometriosis, although the risks of surgery should be balanced against the anticipated benefits. Ovarian retention should be considered for premenopausal women who do not have a genetic predisposition to ovarian cancer. Ovarian epithelial carcinoma may originate in cells from the fallopian tube. Therefore, salpingectomy without oophorectomy may be considered in low-risk women who undergo hysterectomy or other pelvic surgery for benign disease, which reduces the risk of ovarian cancer without the development of surgical menopause (American College of Obstetrics and Gynecologists, Obstet Gynecol 2019, 133: e279-e84; Society of Gynecologic Oncology, SGO Clinical Practice Statement: Salpingectomy for Ovarian Cancer Prevention 2013).

4:
Although robotic-assisted hysterectomy is being done, there are few prospective studies comparing robotic assisted to laparoscopic surgery for treating benign disease (ACOG, Obstetrics and Gynecology Committee Opinion No. 628. 2015, 125: 760-7. Reaffirmed 2017; Yu et al., Journal of surgical oncology 2013, 107: 653-8). A Cochrane review, however, demonstrated that robotic-assisted gynecologic surgery required more intraoperative time but reduced hospital stay when compared to laparoscopic surgery. There is no clear evidence to determine which surgery has the lowest complication rate (Liu et al., The Cochrane database of systematic reviews 2014, 12: CD011422). Robotic-assisted surgery can be performed as an outpatient surgery in some patients (Lawrie et al., Cochrane Database Syst Rev 2019, 4: Cd011422).

5:
Total laparoscopic hysterectomy (TLH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are then secured by the endoscopic route. The fundus is then divided and removed through the abdominal wall incisions.

6:
Vaginal hysterectomy offers many advantages to the abdominal or laparoscopic approach including no abdominal incision, less pain, and quicker recovery; if technically feasible, it is the preferred surgical route (American College of Obstetricians and Gynecologists (ACOG), Obstet Gynecol 2017, 129: e155-e9; Sesti et al., Archives of Gynecology and Obstetrics 2014, 290: 485-91). The vaginal technique, however, can be limited in its ability to treat ovarian pathology in large uteri. The preoperative use of GnRH agonists may help shrink large uteri so that a vaginal hysterectomy can be performed (Elzaher et al., European Journal of Obstetrics, Gynecology, and Reproductive Biology 2013, 169: 326-30). Vaginal hysterectomy may be difficult to perform in nulliparous women, obese women, and women with a history of cesarean delivery.

7:
These criteria include the following procedures:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

8:
Laparoscopically assisted vaginal hysterectomy (LAVH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are not secured by the endoscopic route. A vaginal hysterectomy is then performed.

9:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

10:
For cervical cancer stage I-IIA and endometrial cancer stage II, see the "Hysterectomy, Radical" criteria subset.

11:
Supracervical hysterectomy (subtotal hysterectomy) performed as an open or laparoscopic procedure has been thought to preserve sexual, bladder, and bowel function by minimizing disruption of the pelvic floor support and neurovascular supply when compared with total hysterectomy. However, there is inconsistent evidence to show there is an improvement or significant difference in surgical complications, incontinence rate, bladder function, or sexual function when subtotal hysterectomy is compared to total hysterectomy (Lethaby et al., Cochrane Database Syst Rev 2012, 4: CD004993). One 5-year follow-up study of a randomized controlled trial, however, did show higher rates of urinary incontinence and vaginal bleeding in women who had a supracervical hysterectomy compared with those who had a total hysterectomy (Andersen et al., BJOG: An International Journal of Obstetrics and Gynaecology 2015, 122: 851-7). Disadvantages of supracervical hysterectomy include cervical stump complications (e.g., bleeding, pain) and the small risk of developing cervical cancer in the cervical stump (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013). Supracervical hysterectomy may not be appropriate in women who have gynecological cancers, endometrial hyperplasia, or cervical dysplasia (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013).

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy + BSO for Suspected Ovarian or Tubal cancer

ICD-10-CM (circle all that apply): C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C79.82, D06.0, D06.1, D06.7, D06.9, D25.0, D25.1, D25.2, D25.9, N70.01, N70.02, N70.03, N70.11, N70.12, N70.13, N70.91, N70.92, N70.93, N71.1, N71.9, N72, N73.1, N73.4, N73.8, N73.9, N80.0, N80.1, N80.2, N80.3, N80.4, N80.5, N80.6, N80.8, N80.9, N81.2, N81.3, N81.4, N85.00, N85.01, N85.02, N87.0, N87.1, N87.9, N92.1, N92.4, N92.5, N93.0, N93.1, N93.8, N93.9, N95.0, O01.0, O01.1, O01.9, O72.0, O72.1, O72.2, O72.3, R10.10, R10.11, R10.12, R10.13, R10.2, R10.30, R10.31, R10.32, R10.33, R10.811, R10.812, R10.813, R10.814, R10.815, R10.816, R10.817, R10.819, R10.821, R10.822, R10.823, R10.824, R10.825, R10.826, R10.827, R10.829, R10.83, R10.84, R10.9, R19.00, R19.01, R19.02, R19.03, R19.04, R19.05, R19.06, R19.07, R19.09, R93.5, Z14.8, Z15.01, Z15.02, Z15.04, Z15.09, Z15.89, Other _____

ICD-10-PCS (circle all that apply): 0UT20ZZ, 0UT24ZZ, 0UT70ZZ, 0UT74ZZ, 0UT90ZL, 0UT90ZZ, 0UT94ZL, 0UT94ZZ, 0UTC0ZZ, 0UTC4ZZ, Other _____

CPT® (circle all that apply): 58150, 58152, 58180, 58542, 58544, 58571, 58573, 58575, Other _____

InterQual®

2021, Oct. 2021 Release CP:Procedures

Subset: Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11]

Requested Service: Hysterectomy +/- BSO or Bilateral Salpingectomy for Abnormal uterine bleeding or Postmenopausal bleeding

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:	Date:	
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Choose one of the following options and continue to the appropriate section

- ☐ 10. Abnormal uterine bleeding in premenopausal woman
- ☐ 20. Postmenopausal bleeding

☐ 10. Abnormal uterine bleeding in premenopausal woman

1. Choose all that apply:
   - ☐ A) Abnormal uterine bleeding [12]
   - ☐ B) Vagina and cervix normal by physical examination
   - ☐ C) Thyroid disease excluded by history or physical examination or testing [13]
   - ☐ D) Most recent cervical cytology normal or managed per guidelines [14]
   - ☐ E) Pregnancy excluded by negative human chorionic gonadotropin (HCG) or HCG planned prior to procedure or sterilization by history or patient not sexually active by history [15, 16, 17, 18]
   - ☐ F) Imaging or hysteroscopy within last year negative for endometrial lesion [19]
   - ☐ G) Other clinical information (add comment)

> • If the number of options selected is 6 and option G not selected, then go to question 2
> • No other options lead to the requested service

EXHIBIT 17

DHHRBMS001046

Abnormal uterine bleeding in premenopausal woman (continued...)

2. Choose one: [20]
   - ☐ A) Age < 45
   - ☐ B) Age ≥ 45

   • If option A selected, then go to question 3
   • If option B selected, then go to question 6

3. Choose all that apply: [21]
   - ☐ A) Bleeding interferes with ADLs
   - ☐ B) Anemia by history
   - ☐ C) Other clinical information (add comment)

   • If 1 or more options A or B selected and option C not selected, then go to question 4
   • No other options lead to the requested service

4. Treatment within last year, Choose all that apply:
   - ☐ A) Hormone therapy [22]
   - ☐ B) Tranexamic acid x3 consecutive cycles [23]
   - ☐ C) Endometrial ablation or resection [24]
   - ☐ D) Other clinical information (add comment)

   • If 1 or more options A, B or C selected and option D not selected, then go to question 5
   • No other options lead to the requested service

5. Continued bleeding after treatment
   - ☐ A) Yes
   - ☐ B) No

   • If option Yes selected, then the rule is satisfied; you may stop here [25]
   • No other options lead to the requested service

6. Endometrium normal within last year, Choose all that apply:
   - ☐ A) By endometrial biopsy
   - ☐ B) By hysteroscopy with dilatation and curettage (D & C)
   - ☐ C) Other clinical information (add comment)

   • If 1 or more options A or B selected and option C not selected, then go to question 7
   • No other options lead to the requested service

7. Choose all that apply: [21]
   - ☐ A) Bleeding interferes with ADLs
   - ☐ B) Anemia by history
   - ☐ C) Other clinical information (add comment)

   • If 1 or more options A or B selected and option C not selected, then go to question 8
   • No other options lead to the requested service

Abnormal uterine bleeding in premenopausal woman (continued...)

8. Treatment within last year, Choose all that apply:
   - ☐ A) Hormone therapy [22]
   - ☐ B) Tranexamic acid x3 consecutive cycles [23]
   - ☐ C) Endometrial ablation or resection [24]
   - ☐ D) Other clinical information (add comment)

   • If 1 or more options A, B or C selected and option D not selected, then go to question 9
   • No other options lead to the requested service

9. Continued bleeding after treatment
   - ☐ A) Yes
   - ☐ B) No

   • If option Yes selected, then the rule is satisfied; you may stop here [25]
   • No other options lead to the requested service

☐ 20. Postmenopausal bleeding

1. Choose all that apply:
   - ☐ A) Vagina and cervix normal by physical examination
   - ☐ B) Most recent cervical cytology normal or managed per guidelines [14]
   - ☐ C) Endometrium normal within last 3 months by biopsy and ultrasound
   - ☐ D) Other clinical information (add comment)

   • If the number of options selected is 3 and option D not selected, then go to question 2
   • No other options lead to the requested service

2. Currently taking hormone replacement therapy [26]
   - ☐ A) Yes
   - ☐ B) No

   • If option No selected, then the rule is satisfied; you may stop here [25]
   • If option Yes selected, then go to question 3

3. Continued abnormal bleeding after, Choose one: [27]
   - ☐ A) Change in hormone replacement therapy
   - ☐ B) Discontinuation of hormone replacement therapy
   - ☐ C) Other clinical information (add comment)

   • If option A or B selected, then the rule is satisfied; you may stop here [25]
   • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

3:
Whether to perform prophylactic oophorectomy at the time of hysterectomy done for benign disease in premenopausal women may be considered. There are no published randomized studies to support conservation or prophylactic removal of the ovaries, although observational studies suggest that surgical menopause may increase cardiovascular and overall mortality risk (Orozco et al., The Cochrane database of systematic reviews 2014, 7: CD005638). Generally, bilateral salpingo-oophorectomy (BSO) is recommended for women with BRCA1 or BRCA2 mutations or Lynch syndrome, for postmenopausal women, and for women who have invasive endometrial or ovarian carcinoma (National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: breast and ovarian (Version 3.2019). 2019; National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: colorectal (Version 3.2019). 2019). BSO may also be considered in women who have chronic pelvic pain, pelvic inflammatory disease, or endometriosis, although the risks of surgery should be balanced against the anticipated benefits. Ovarian retention should be considered for premenopausal women who do not have a genetic predisposition to ovarian cancer. Ovarian epithelial carcinoma may originate in cells from the fallopian tube. Therefore, salpingectomy without oophorectomy may be considered in low-risk women who undergo hysterectomy or other pelvic surgery for benign disease, which reduces the risk of ovarian cancer without the development of surgical menopause (American College of Obstetrics and Gynecologists, Obstet Gynecol 2019, 133: e279-e84; Society of Gynecologic Oncology, SGO Clinical Practice Statement: Salpingectomy for Ovarian Cancer Prevention 2013).

4:
Although robotic-assisted hysterectomy is being done, there are few prospective studies comparing robotic assisted to laparoscopic surgery for treating benign disease (ACOG, Obstetrics and Gynecology Committee Opinion No. 628. 2015, 125: 760-7. Reaffirmed 2017; Yu et al., Journal of surgical oncology 2013, 107: 653-8). A Cochrane review, however, demonstrated that robotic-assisted gynecologic surgery required more intraoperative time but reduced hospital stay when compared to laparoscopic surgery. There is no clear evidence to determine which surgery has the lowest complication rate (Liu et al., The Cochrane database of systematic reviews 2014, 12: CD011422). Robotic-assisted surgery can be performed as an outpatient surgery in some patients (Lawrie et al., Cochrane Database Syst Rev 2019, 4: Cd011422).

5:
Total laparoscopic hysterectomy (TLH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are then secured by the endoscopic route. The fundus is then divided and removed through the abdominal wall incisions.

6:
Vaginal hysterectomy offers many advantages to the abdominal or laparoscopic approach including no abdominal incision, less pain, and quicker recovery; if technically feasible, it is the preferred surgical route (American College of Obstetricians and Gynecologists (ACOG), Obstet Gynecol 2017, 129: e155-e9; Sesti et al., Archives of Gynecology and Obstetrics 2014, 290: 485-91). The vaginal technique, however, can be limited in its ability to treat ovarian pathology in large uteri. The preoperative use of GnRH agonists may help shrink large uteri so that a vaginal hysterectomy can be performed (Elzaher et al., European Journal of Obstetrics, Gynecology, and Reproductive Biology 2013, 169: 326-30). Vaginal hysterectomy may be difficult to perform in nulliparous women, obese women, and women with a history of cesarean delivery.

7:
These criteria include the following procedures:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

8:
Laparoscopically assisted vaginal hysterectomy (LAVH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are not secured by the endoscopic route. A vaginal hysterectomy is then performed.

9:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

10:
For cervical cancer stage I-IIA and endometrial cancer stage II, see the "Hysterectomy, Radical" criteria subset.

11:
Supracervical hysterectomy (subtotal hysterectomy) performed as an open or laparoscopic procedure has been thought to preserve sexual, bladder, and bowel function by minimizing disruption of the pelvic floor support and neurovascular supply when compared with total hysterectomy. However, there is inconsistent evidence to show there is an improvement or significant difference in surgical complications, incontinence rate, bladder function, or sexual function when subtotal hysterectomy is compared to total hysterectomy (Lethaby et al., Cochrane Database Syst Rev 2012, 4: CD004993). One 5-year follow-up study of a randomized controlled trial, however, did show higher rates of urinary incontinence and vaginal bleeding in women who had a supracervical hysterectomy compared with those who had a total hysterectomy (Andersen et al., BJOG: An International Journal of Obstetrics and Gynaecology 2015, 122: 851-7). Disadvantages of supracervical hysterectomy include cervical stump complications (e.g., bleeding, pain) and the small risk of developing cervical cancer in the cervical stump (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013). Supracervical hysterectomy may not be appropriate in women who have gynecological cancers, endometrial hyperplasia, or cervical dysplasia (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013).

12:
Abnormal uterine bleeding includes menorrhagia (heavy and prolonged menses) and menometrorrhagia (heavy and prolonged bleeding during and between menses).

13:
Hypothyroidism or hyperthyroidism may cause a variety of menstrual irregularities such as menorrhagia (heavy and prolonged menses), amenorrhea (no menses), or oligomenorrhea (scant menses). Documentation to exclude a thyroid disorder as a cause of the bleeding may be performed at any time in the workup of the patient.

14:
Cervical cytology should be evaluated according to current screening protocols. Screening intervals and tests used (cervical cytology alone, high-risk human papillomavirus [hrHPV] testing alone, hrHPV and cytology together [co-testing]) will vary based on patient's age and risk factors. If the most recent cervical cytology is documented as normal, no further testing is needed. Any abnormalities detected during cervical cancer screening should be managed according to current guidelines. Management may include repeat testing, observation, surveillance, biopsy, ablation, or excisional treatment based on the identified level of risk for each patient (Redman et al., Eur J Obstet Gynecol Reprod Biol 2021, 256: 57-62; Perkins et al., J Low Genit Tract Dis 2020, 24: 102-31; US Preventative Services Task Force et al., JAMA 2018, 320: 674-86; Wentzensen et al., J Low Genit Tract Dis 2017, 21: 216-22).

15:
Pregnancy and related complications (e.g., ectopic pregnancy, incomplete abortion, inevitable abortion) must be excluded before performing this procedure.

16:
Pregnancy testing can be by measurement of either a serum or urine HCG and may be documented in the medical record by either the primary care physician, gynecologist, or surgeon.

17:
The documentation should include a history of sterilization (i.e., tubal ligation) without a subsequent pregnancy. These criteria do not include sterilization of a partner or alternate birth control methods (e.g., oral contraceptive pill use, intrauterine device insertion).

18:
Patients have varying definitions of sexual activity (e.g., number of partners, timing of most recent episode, frequency of sexual activity). Unless the provider can confirm on examination that the patient has never had sexual intercourse, whether a patient is sexually active or not is a matter of clinical judgment.

19:
Imaging studies (e.g., ultrasound, sonohysterogram) are performed to exclude a structural cause of the uterine bleeding. Direct examination by hysteroscopy can also evaluate and eliminate structural abnormalities.

20:
The incidence of endometrial cancer increases with age. Women over the age of 45 tend to have a worse prognosis and often have less differentiated, more advanced stage disease. Therefore, endometrial biopsy should be performed in women with abnormal uterine bleeding 45 years of age or older to exclude premalignant lesions, carcinoma, or other pathology that may cause bleeding (ACOG, Obstet Gynecol Practice Bulletin No. 128. 2012, 120: 197-206. Reaffirmed 2016; ACOG, Obstetrics and gynecology Practice Bulleting No. 136. 2013, 122: 176-185. Reaffirmed 2018). Biopsy may also be considered in women as young as 40 or in those whose bleeding does not improve with hormonal or other therapy (Singh et al., Journal of obstetrics and gynaecology Canada: JOGC 2013, 35: 473-9). If a hysterectomy is to be performed, the biopsy results will guide what type of surgery should be performed (ACOG, Obstetrics and gynecology Practice Bulleting No. 136. 2013, 122: 176-185. Reaffirmed 2018).

21:
Abnormal uterine bleeding is considered significant enough to warrant intervention when there is documented anemia by history (currently has anemia or has been treated for anemia related to the bleeding) or bleeding

significantly impacts quality of life. The International Federation of Gynecology and Obstetrics classification system for abnormal uterine bleeding provides a framework to evaluate and manage this condition. This system helps identify the cause of bleeding as either structural (e.g., polyp, adenomyosis, leiomyoma, malignancy/hyperplasia) or unrelated to structure (e.g., coagulopathy, ovulatory dysfunction, endometrial, iatrogenic) and then formulate an individual plan of care (Kolhe, Int J Womens Health 2018, 10: 127-36).

22:
Hormone therapy to treat abnormal uterine bleeding includes cyclic or continuous combined oral contraceptive or progestin only hormone therapy (ACOG, Obstetrics and gynecology Practice Bulletin No. 110. 2010, 115: 206-218. Reaffirmed 2018; ACOG, Obstetrics and gynecology Practice Bulleting No. 136. 2013, 122: 176-185. Reaffirmed 2018; Singh et al., Journal of obstetrics and gynaecology Canada: JOGC 2013, 35: 473-9). Oral medication, a dermal patch, or vaginal ring may be used. The levonorgestrel releasing intrauterine system has been shown to significantly reduce bleeding and cramping, and may be considered a first-line treatment for women with heavy abnormal bleeding (ACOG, Obstetrics and gynecology Practice Bulletin No. 110. 2010, 115: 206-218. Reaffirmed 2018; Gupta et al., N Engl J Med 2013, 368: 128-37; Heliovaara-Peippo et al., American journal of obstetrics and gynecology 2013, 209: 535 e1- e14; Singh et al., Journal of obstetrics and gynaecology Canada: JOGC 2013, 35: 473-9). For those who cannot tolerate or did not have success on other therapies or who are not surgical candidates, danazol and GnRH agonists may be options (Singh et al., Journal of obstetrics and gynaecology Canada: JOGC 2013, 35: 473-9).

23:
Tranexamic acid is an antifibrinolytic taken during menstruation and has been shown to be an effective treatment to decrease heavy abnormal uterine bleeding and improve quality of life (Singh et al., Journal of obstetrics and gynaecology Canada: JOGC 2013, 35: 473-9).

24:
If medical therapy fails or is not an option for abnormal uterine bleeding, hysteroscopic endometrial resection or ablation may be performed as an alternative to hysterectomy (Fergusson et al., Cochrane Database Syst Rev 2019, 8: Cd000329; Obstet Gynecol Practice Bulletin No. 81 2007; 109(5): 1233-1248. Reaffirmed 2018).
Nonhysteroscopic techniques for endometrial ablation (e.g., thermal balloon, cryoablation, microwave, electrode ablation) have also been shown to be beneficial for the treatment of abnormal uterine bleeding (Fergusson et al., Cochrane Database Syst Rev 2019, 8: Cd000329; Singh et al., Journal of obstetrics and gynaecology Canada: JOGC 2013, 35: 473-9).

25:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

26:
The risks and benefits of long-term hormone replacement therapy use should be carefully considered for each patient, as the benefit changes with age, menopausal symptoms, comorbidities, and the presence of risk factors for adverse outcomes (e.g., stroke, coronary artery disease). Review of major studies, such as the Heart and Estrogen/Progestin Replacement Study Follow-Up (HERS) and the Women's Health Initiative (WHI), indicates the risk-benefit ratio for hormone therapy is most favorable if it is initiated closer to menopause. This benefit decreases in older women and in women who are more temporally removed from menopause (North American Menopause Society, Menopause 2017, 24: 728-53).

27:

Postmenopausal bleeding should always be investigated, as it could be a sign of endometrial cancer (American College of Obstetricians and Gynecologists, Obstet Gynecol 2018, 131: 945-6; ACOG, Obstetrics and gynecology ACOG Practice Bulletin No. 149, 2015, 125: 1006-26. Reaffirmed 2019; Khati et al., ACR Appropriateness Criteria((R)) Abnormal Vaginal Bleeding. 2014). Postmenopausal bleeding is defined as bleeding after 1 year of amenorrhea in a woman not receiving hormone replacement therapy or unexpected bleeding in patients receiving cyclic hormone therapy or bleeding after 1 year of continuous hormone therapy.

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy +/- BSO or Bilateral Salpingectomy for Abnormal uterine bleeding or Postmenopausal bleeding

ICD-10-CM (circle all that apply): C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C79.82, D06.0, D06.1, D06.7, D06.9, D25.0, D25.1, D25.2, D25.9, N70.01, N70.02, N70.03, N70.11, N70.12, N70.13, N70.91, N70.92, N70.93, N71.1, N71.9, N72, N73.1, N73.4, N73.8, N73.9, N80.0, N80.1, N80.2, N80.3, N80.4, N80.5, N80.6, N80.8, N80.9, N81.2, N81.3, N81.4, N85.00, N85.01, N85.02, N87.0, N87.1, N87.9, N92.1, N92.4, N92.5, N93.0, N93.1, N93.8, N93.9, N95.0, O01.0, O01.1, O01.9, O72.0, O72.1, O72.2, O72.3, R10.10, R10.11, R10.12, R10.13, R10.2, R10.30, R10.31, R10.32, R10.33, R10.811, R10.812, R10.813, R10.814, R10.815, R10.816, R10.817, R10.819, R10.821, R10.822, R10.823, R10.824, R10.825, R10.826, R10.827, R10.829, R10.83, R10.84, R10.9, R19.00, R19.01, R19.02, R19.03, R19.04, R19.05, R19.06, R19.07, R19.09, R93.5, Z14.8, Z15.01, Z15.02, Z15.04, Z15.09, Z15.89, Other _____

ICD-10-PCS (circle all that apply): 0UT20ZZ, 0UT24ZZ, 0UT27ZZ, 0UT28ZZ, 0UT2FZZ, 0UT70ZZ, 0UT74ZZ, 0UT77ZZ, 0UT78ZZ, 0UT7FZZ, 0UT90ZL, 0UT90ZZ, 0UT94ZL, 0UT94ZZ, 0UT97ZL, 0UT97ZZ, 0UT98ZL, 0UT98ZZ, 0UT9FZL, 0UT9FZZ, 0UTC0ZZ, 0UTC4ZZ, 0UTC7ZZ, 0UTC8ZZ, Other _____

CPT® (circle all that apply): 58150, 58152, 58180, 58260, 58262, 58263, 58290, 58291, 58292, 58541, 58542, 58543, 58544, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573, 58575, Other _____

InterQual®

2021, Oct. 2021 Release CP:Procedures

Subset: Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11]

Requested Service: Hysterectomy +/- BSO or Bilateral Salpingectomy for Adenomyosis or Fibroids

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:	Date:	
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Choose one of the following options and continue to the appropriate section

- ☐ 10. Adenomyosis suspected by imaging
- ☐ 20. Fibroids by imaging in postmenopausal woman
- ☐ 30. Fibroids by imaging in premenopausal woman

☐ 10. Adenomyosis suspected by imaging

1. Choose one: [12]
   - ☐ A) Abnormal bleeding [13]
   - ☐ B) Pelvic or abdominal pain or discomfort and other etiologies excluded [14]
   - ☐ C) Urinary frequency or urgency and other etiologies excluded
   - ☐ D) Dyspareunia [15]
   - ☐ E) Other clinical information (add comment)

> • If option A selected, then go to question 2
> • If option B, C or D selected, then go to question 4
> • No other options lead to the requested service

Adenomyosis suspected by imaging (continued...)

2. Choose all that apply: [16]
   - ☐ A) Vagina and cervix normal by physical examination
   - ☐ B) Pregnancy excluded by negative HCG or HCG planned prior to procedure or sterilization by history or patient not sexually active by history
   - ☐ C) Other clinical information (add comment)

   • If the number of options selected is 2 and option C not selected, then go to question 3
   • No other options lead to the requested service

3. Choose all that apply: [17]
   - ☐ A) Bleeding interferes with ADLs
   - ☐ B) Anemia by history
   - ☐ C) Other clinical information (add comment)

   • If 1 or more options A or B selected and option C not selected, then go to question 4
   • No other options lead to the requested service

4. Treatment within last year, Choose all that apply: [18]
   - ☐ A) NSAIDs ≥ 8 weeks
   - ☐ B) GnRH agonist ≥ 8 weeks [19]
   - ☐ C) Hormone therapy ≥ 8 weeks
   - ☐ D) Uterine artery embolization
   - ☐ E) Other clinical information (add comment)

   • If 1 or more options A, B, C or D selected and option E not selected, then go to question 5
   • No other options lead to the requested service

5. Continued symptoms or findings after treatment
   - ☐ A) Yes
   - ☐ B) No

   • If option Yes selected, then go to question 6
   • No other options lead to the requested service

6. Choose all that apply:
   - ☐ A) Most recent cervical cytology normal or managed per guidelines [20]
   - ☐ B) Pregnancy excluded by negative HCG or HCG planned prior to procedure or sterilization by history or patient not sexually active by history [21, 22, 23, 24]
   - ☐ C) Other clinical information (add comment)

   • If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here [25]
   • No other options lead to the requested service

☐ 20. Fibroids by imaging in postmenopausal woman

Fibroids by imaging in postmenopausal woman (continued...)

1. Choose all that apply: [26, 27]
   - ☐ A) Uterine size doubled by ultrasound within 1 year
   - ☐ B) Ureteral compression by imaging [28]
   - ☐ C) Pelvic or abdominal pain or discomfort and other etiologies excluded
   - ☐ D) Urinary frequency or urgency and other etiologies excluded
   - ☐ E) Dyspareunia and other etiologies excluded [15]
   - ☐ F) Other clinical information (add comment)

   • If 1 or more options A, B, C, D or E selected and option F not selected, then go to question 2
   • No other options lead to the requested service

2. Most recent cervical cytology normal or managed per guidelines [20]
   - ☐ A) Yes
   - ☐ B) No

   • If option Yes selected, then go to question 3
   • No other options lead to the requested service

3. Laparoscopic power morcellation planned with hysterectomy [29]
   - ☐ A) Yes
   - ☐ B) No

   • If option No selected, then the rule is satisfied; you may stop here [25]
   • No other options lead to the requested service

☐ 30. Fibroids by imaging in premenopausal woman

1. Choose one: [27]
   - ☐ A) Abnormal uterine bleeding with anemia by history or interferes with ADLs [13, 17]
   - ☐ B) Uterine size doubled by ultrasound (US) within 1 year [30]
   - ☐ C) Ureteral compression by imaging [28]
   - ☐ D) Pelvic or abdominal pain or discomfort and other etiologies excluded
   - ☐ E) Urinary frequency or urgency and other etiologies excluded
   - ☐ F) Dyspareunia and other etiologies excluded [15]
   - ☐ G) Other clinical information (add comment)

   • If option A selected, then go to question 2
   • If option B, C, D, E or F selected, then go to question 3
   • No other options lead to the requested service

2. Vagina and cervix normal by physical examination [31]
   - ☐ A) Yes
   - ☐ B) No

   • If option Yes selected, then go to question 3
   • No other options lead to the requested service

Fibroids by imaging in premenopausal woman (continued...)

3. Choose all that apply:
   - ☐ A) Most recent cervical cytology normal or managed per guidelines [20]
   - ☐ B) Pregnancy excluded by negative HCG or HCG planned prior to procedure or sterilization by history or patient not sexually active by history [21, 22, 23, 24]
   - ☐ C) Other clinical information (add comment)

   - If the number of options selected is 2 and option C not selected, then go to question 4
   - No other options lead to the requested service

4. Laparoscopic power morcellation planned with hysterectomy [32, 33]
   - ☐ A) Yes
   - ☐ B) No

   - If option No selected, then the rule is satisfied; you may stop here [25]
   - If option Yes selected, then go to question 5

5. Choose all that apply:
   - ☐ A) No known or suspected malignancy by testing in tissue to be morcellated [34]
   - ☐ B) Not a candidate for **en bloc** or intact tissue removal [35]
   - ☐ C) Other clinical information (add comment)

   - If the number of options selected is 2 and option C not selected, then go to question 6
   - No other options lead to the requested service

6. Increased risk for uterine malignancy, Choose one:
   - ☐ A) Pelvic irradiation by history
   - ☐ B) Tamoxifen use by history
   - ☐ C) Lynch ll syndrome
   - ☐ D) Hereditary leiomyomatosis and renal cell cancer
   - ☐ E) Childhood retinoblastoma by history
   - ☐ F) Postmenopausal with fibroids by imaging [36]
   - ☐ G) None of the above, more choices

   - If option G selected, then go to question 7
   - No other options lead to the requested service

7. Risks and benefits of morcellation discussed with patient [37]
   - ☐ A) Yes
   - ☐ B) No

   - If option Yes selected, then the rule is satisfied; you may stop here [25]
   - No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

3:
Whether to perform prophylactic oophorectomy at the time of hysterectomy done for benign disease in premenopausal women may be considered. There are no published randomized studies to support conservation or prophylactic removal of the ovaries, although observational studies suggest that surgical menopause may increase cardiovascular and overall mortality risk (Orozco et al., The Cochrane database of systematic reviews 2014, 7: CD005638). Generally, bilateral salpingo-oophorectomy (BSO) is recommended for women with BRCA1 or BRCA2 mutations or Lynch syndrome, for postmenopausal women, and for women who have invasive endometrial or ovarian carcinoma (National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: breast and ovarian (Version 3.2019). 2019; National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: colorectal (Version 3.2019). 2019). BSO may also be considered in women who have chronic pelvic pain, pelvic inflammatory disease, or endometriosis, although the risks of surgery should be balanced against the anticipated benefits. Ovarian retention should be considered for premenopausal women who do not have a genetic predisposition to ovarian cancer. Ovarian epithelial carcinoma may originate in cells from the fallopian tube. Therefore, salpingectomy without oophorectomy may be considered in low-risk women who undergo hysterectomy or other pelvic surgery for benign disease, which reduces the risk of ovarian cancer without the development of surgical menopause (American College of Obstetrics and Gynecologists, Obstet Gynecol 2019, 133: e279-e84; Society of Gynecologic Oncology, SGO Clinical Practice Statement: Salpingectomy for Ovarian Cancer Prevention 2013).

4:
Although robotic-assisted hysterectomy is being done, there are few prospective studies comparing robotic assisted to laparoscopic surgery for treating benign disease (ACOG, Obstetrics and Gynecology Committee Opinion No. 628. 2015, 125: 760-7. Reaffirmed 2017; Yu et al., Journal of surgical oncology 2013, 107: 653-8). A Cochrane review, however, demonstrated that robotic-assisted gynecologic surgery required more intraoperative time but reduced hospital stay when compared to laparoscopic surgery. There is no clear evidence to determine which surgery has the lowest complication rate (Liu et al., The Cochrane database of systematic reviews 2014, 12: CD011422). Robotic-assisted surgery can be performed as an outpatient surgery in some patients (Lawrie et al., Cochrane Database Syst Rev 2019, 4: Cd011422).

5:
Total laparoscopic hysterectomy (TLH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are then secured by the endoscopic route. The fundus is then divided and removed through the abdominal wall incisions.

6:
Vaginal hysterectomy offers many advantages to the abdominal or laparoscopic approach including no abdominal incision, less pain, and quicker recovery; if technically feasible, it is the preferred surgical route (American College of Obstetricians and Gynecologists (ACOG), Obstet Gynecol 2017, 129: e155-e9; Sesti et al., Archives of Gynecology and Obstetrics 2014, 290: 485-91). The vaginal technique, however, can be limited in its ability to treat ovarian pathology in large uteri. The preoperative use of GnRH agonists may help shrink large uteri so that a vaginal hysterectomy can be performed (Elzaher et al., European Journal of Obstetrics, Gynecology, and Reproductive Biology 2013, 169: 326-30). Vaginal hysterectomy may be difficult to perform in nulliparous women, obese women, and women with a history of cesarean delivery.

7:
These criteria include the following procedures:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

8:
Laparoscopically assisted vaginal hysterectomy (LAVH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are not secured by the endoscopic route. A vaginal hysterectomy is then performed.

9:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

10:
For cervical cancer stage I-IIA and endometrial cancer stage II, see the "Hysterectomy, Radical" criteria subset.

11:
Supracervical hysterectomy (subtotal hysterectomy) performed as an open or laparoscopic procedure has been thought to preserve sexual, bladder, and bowel function by minimizing disruption of the pelvic floor support and neurovascular supply when compared with total hysterectomy. However, there is inconsistent evidence to show there is an improvement or significant difference in surgical complications, incontinence rate, bladder function, or sexual function when subtotal hysterectomy is compared to total hysterectomy (Lethaby et al., Cochrane Database Syst Rev 2012, 4: CD004993). One 5-year follow-up study of a randomized controlled trial, however, did show higher rates of urinary incontinence and vaginal bleeding in women who had a supracervical hysterectomy compared with those who had a total hysterectomy (Andersen et al., BJOG: An International Journal of Obstetrics and Gynaecology 2015, 122: 851-7). Disadvantages of supracervical hysterectomy include cervical stump complications (e.g., bleeding, pain) and the small risk of developing cervical cancer in the cervical stump (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013). Supracervical hysterectomy may not be appropriate in women who have gynecological cancers, endometrial hyperplasia, or cervical dysplasia (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013).

12:
There are no symptoms that are pathognomonic for adenomyosis and many of the symptoms are associated with other common gynecologic disorders (e.g., fibroids, abnormal uterine bleeding, endometriosis).

13:
Abnormal uterine bleeding includes menorrhagia (heavy and prolonged menses) and menometrorrhagia (heavy and prolonged bleeding during and between menses).

14:
The pain associated with adenomyosis is varied and includes cramping that may begin days or weeks prior to menses, dyspareunia, or dysuria.

15:
Dyspareunia is difficult or painful sexual intercourse.

16:
A history and laboratory assessment to evaluate vaginal bleeding can help exclude systemic conditions, coagulopathy, and medication or thyroid dysfunction, while the physical examination excludes vaginal or cervical causes of bleeding.

17:
Abnormal uterine bleeding is considered significant enough to warrant intervention when there is documented anemia by history (currently has anemia or has been treated for anemia related to the bleeding) or bleeding significantly impacts quality of life. The International Federation of Gynecology and Obstetrics classification system for abnormal uterine bleeding provides a framework to evaluate and manage this condition. This system helps identify the cause of bleeding as either structural (e.g., polyp, adenomyosis, leiomyoma, malignancy/hyperplasia) or unrelated to structure (e.g., coagulopathy, ovulatory dysfunction, endometrial, iatrogenic) and then formulate an individual plan of care (Kolhe, Int J Womens Health 2018, 10: 127-36).

18:
Although hysterectomy is an effective treatment for symptomatic adenomyosis, medical treatment options include progestin, the levonorgestrel intra-uterine system, GnRH agonists, and nonsteroidal anti-inflammatory drugs (ACOG, Obstetrics and gynecology Practice Bulletin No. 110. 2010, 115: 206-218. Reaffirmed 2018; Streuli et al., Expert opinion on pharmacotherapy 2014, 15: 2347-60). Surgical options include uterine artery embolization and uterine artery occlusion with partial resection (Nijenhuis et al., Cardiovascular and interventional radiology 2015, 38: 65-71; Liu et al., European journal of obstetrics, gynecology, and reproductive biology 2014, 176: 20-4; Smeets et al., Cardiovascular and interventional radiology 2012, 35: 815-9).

19:
The GnRH agonists include leuprolide, nafarelin, and goserelin. These compounds mimic the action of GnRH and, thereby, suppress the hormones produced by the ovary that stimulate endometrial growth.

20:
Cervical cytology should be evaluated according to current screening protocols. Screening intervals and tests used (cervical cytology alone, high-risk human papillomavirus [hrHPV] testing alone, hrHPV and cytology together [co-testing]) will vary based on patient's age and risk factors. If the most recent cervical cytology is documented as normal, no further testing is needed. Any abnormalities detected during cervical cancer screening should be managed according to current guidelines. Management may include repeat testing, observation, surveillance, biopsy, ablation, or excisional treatment based on the identified level of risk for each patient (Redman et al., Eur J Obstet Gynecol Reprod Biol 2021, 256: 57-62; Perkins et al., J Low Genit Tract Dis 2020, 24: 102-31; US Preventative Services Task Force et al., JAMA 2018, 320: 674-86; Wentzensen et al., J Low Genit Tract Dis 2017, 21: 216-22).

21:
Pregnancy and related complications (e.g., ectopic pregnancy, incomplete abortion, inevitable abortion) must be excluded before performing this procedure.

22:
Pregnancy testing can be performed by measurement of either a serum or urine HCG and may be documented in the medical record by either the PCP, a gynecologist, or a surgeon.

23:
The documentation should include a history of sterilization (i.e., tubal ligation) without a subsequent pregnancy. These criteria do not include sterilization of a partner or alternate birth control methods (e.g., oral contraceptive pill use, intrauterine device insertion).

24:
Patients have varying definitions of sexual activity (e.g., number of partners, timing of most recent episode, frequency of sexual activity). Unless the provider can confirm on examination that the patient has never had sexual intercourse, whether a patient is sexually active or not is a matter of clinical judgment.

25:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy- Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

26:
If fibroids are associated with postmenopausal bleeding, see the "Postmenopausal bleeding" indication within this criteria subset.

27:
Common pelvic pressure symptoms associated with uterine fibroids include pain, pressure, dyspareunia, and urinary frequency or urgency. These symptoms must be directly attributed to uterine enlargement due to fibroids and other potential causes need to be excluded prior to surgical intervention.

28:
Ureteral compression may be seen at the time of ultrasound.

29:
Power morcellation, which causes intraperitoneal dissemination of myometrium, should never be done for fibroids in postmenopausal women because the incidence of cancer is higher in these women (American College of Obstetricians and Gynecologists, Obstet Gynecol 2019, 133: e238-e48; U.S. Food and Drug Administration (FDA), Updated Assessment of The Use of Laparoscopic Power Morcellators to Treat Uterine Fibroids, December 2017).

30:
Rapid growth of uterine fibroids alone in premenopausal women is not a reliable sign of malignant transformation. Uterine sarcoma is rare and the symptoms are similar to benign fibroids. Imaging and endometrial biopsy may help with the diagnosis, but it is often discovered postoperatively.

31:
Abnormal uterine bleeding due to vaginal, cervical, endometrial, or ovarian conditions may raise the suspicion of malignancy. Bleeding from conditions other than fibroids (e.g., polyps, malignancy) should be excluded prior to the procedure. Testing preprocedure to exclude other etiologies of bleeding may include evaluation for cervical pathology (e.g., Pap smear), imaging, and in some cases endometrial biopsy.

32:
When performing a totally laparoscopic or vaginal procedure, it may be necessary to divide, or morcellate, the specimen to remove it. There is concern that morcellation may result in contamination of the wound, which can lead to upstaging of occult malignancy, iatrogenic endometriosis, or parasitic leiomyomata. The Food and Drug Administration (FDA) reports there is evidence for differences in disease recurrence and survival between women undergoing morcellation and those who do not (U.S. Food and Drug Administration (FDA), Updated Assessment of The Use of Laparoscopic Power Morcellators to Treat Uterine Fibroids, December 2017; Beckmann et al., Geburtshilfe und Frauenheilkunde 2015, 75: 148-64; Pereira et al., Journal of minimally invasive gynecology 2015, 22: 163-76; Siedhoff et al., American journal of obstetrics and gynecology 2015, 212: 591 e1-8; Singh et al., J Obstet Gynaecol Can 2015, 37: 68-81; Vilos et al., Journal of obstetrics and gynaecology Canada: JOGC 2015, 37: 157-81; American Association of Gynecologic Laparoscopists, Journal of minimally invasive gynecology AAGL practice report Morcellation 2014, 21: 517-30). Cohort studies and meta-analyses show a low prevalence of occult malignancy in hysterectomy and myomectomy specimens, including specimens that have undergone morcellation (Bojahr et al., Arch Gynecol Obstet 2015, 292(3): 665-72; Brohl et al., The Oncologist 2015, 20: 433-9; Lieng et al., Journal of minimally invasive gynecology 2015, 22: 410-4; Mahnert et al., Obstetrics and gynecology 2015, 125: 397-405; Singh et al., J Obstet Gynaecol Can 2015, 37: 68-81; Tan-Kim et al., American journal of obstetrics and gynecology 2015, 212: 594 e1-10; Wright et al., JAMA 2014, 312: 1253-5). Data regarding the risk of upstaging of occult malignancy are mixed (Beckmann et al., Geburtshilfe und Frauenheilkunde 2015, 75: 148-64; Bojahr et al., Arch Gynecol Obstet 2015, 292(3): 665-72; Pritts et al., Journal of minimally invasive gynecology 2015, 22: 26-33; George et al., Cancer 2014, 120: 3154-8). The American College of Obstetricians and Gynecologist and others maintains that, with proper evaluation and limiting morcellation to nonmalignant conditions, minimally invasive surgery continues to have a place in the treatment of fibroids (Brolmann et al., Gynecol Surg 2015, 12: 3-15; Singh et al., J Obstet Gynaecol Can 2015, 37: 68-81; ACOG, Power Morcellation and Occult Malignancy in Gynecologic Surgery: A Special Report. 2014). The FDA recommends against the use of laparoscopic power morcellators during myomectomy or hysterectomy when the tissue to be morcellated is known or suspected to contain malignancy, in women who are peri- or post-menopausal with uterine tissue that contains suspected fibroids, or in candidates for en bloc tumor resection or intact tissue removal by a vaginal, laparoscopic port, or mini-laparotomy approach (U.S. Food and Drug Administration (FDA), Updated Assessment of The Use of Laparoscopic Power Morcellators to Treat Uterine Fibroids, December 2017). Additional contraindications to morcellation include known or suspected malignancy, prophylactic surgery for high cancer risk genetic conditions, and history of therapy known to increase cancer risk, such as radiation or tamoxifen (Sizzi et al., Eur J Obstet Gynecol Reprod Biol 2018, 220: 30-8; U.S. Food and Drug Administration (FDA), Updated Assessment of The Use of Laparoscopic Power Morcellators to Treat Uterine Fibroids, December 2017; Beckmann et al., Geburtshilfe und Frauenheilkunde 2015, 75: 148-64; Singh et al., J Obstet Gynaecol Can 2015, 37: 68-81; American Association of Gynecologic Laparoscopists, Journal of minimally invasive gynecology AAGL practice report Morcellation 2014, 21: 517-30; American Urogynecologic Society, AUGS position statement on Power Morcellation 2014).

33:
The Food and Drug Administration safety warning addresses the risks associated with laparoscopic power morcellators that are inserted into the peritoneal cavity and not those that are inserted into the uterus via hysteroscope. These are considered different procedures with different risk profiles. There is no evidence that hysteroscopic morcellation results in the spread of malignant cells (U.S. Food and Drug Administration (FDA), Updated Assessment of The Use of Laparoscopic Power Morcellators to Treat Uterine Fibroids, December 2017; National Institute for Health and Clinical Excellence (NICE). Hysteroscopic morcellation of uterine leiomyomas (fibroids), June 2015).

34:
Prior to hysterectomy or myomectomy with morcellation, women should be evaluated for coexisting uterine or cervical malignancy. Preoperative evaluation for uterine sarcomas has limitations and cannot reliably detect unexpected cancers; however, suspected or known uterine cancer should not be removed by morcellation. In addition to cervical cytology, endometrial assessment may include tissue sampling, ultrasound, or MRI. CT and PET are less effective in differentiating between leiomyoma and uterine leiomyosarcoma (American College of Obstetricians and Gynecologists, Obstet Gynecol 2019, 133: e238-e48; Sizzi et al., Eur J Obstet Gynecol Reprod Biol 2018, 220: 30-8; U.S. Food and Drug Administration (FDA), Updated Assessment of The Use of Laparoscopic Power Morcellators to Treat Uterine Fibroids, December 2017).

35:
En bloc tissue removal or removing tissue as an intact specimen reduces the risk of dissemination and upstaging an

occult sarcoma. Routine use of laparoscopic power morcellators is not recommended when en bloc resection through a vaginal, laparoscopic, or mini-laparotomy approach is a viable option (U.S. Food and Drug Administration (FDA), Updated Assessment of The Use of Laparoscopic Power Morcellators to Treat Uterine Fibroids, December 2017; ACOG, Power Morcellation and Occult Malignancy in Gynecologic Surgery: A Special Report. 2014).

36:
Increased age is considered a risk factor for the development of uterine sarcoma. Therefore, peri- or postmenopausal women with uterine tissue containing fibroids should not undergo laparoscopic power morcellation (American College of Obstetricians and Gynecologists, Obstet Gynecol 2019, 133: e238-e48; U.S. Food and Drug Administration (FDA), Updated Assessment of The Use of Laparoscopic Power Morcellators to Treat Uterine Fibroids, December 2017).

37:
Patients should be counseled regarding the benefits, risks (including the potential for the spread of occult malignancy which may decrease survival), and alternatives when morcellation is planned (American College of Obstetricians and Gynecologists, Obstet Gynecol 2019, 133: e238-e48; U.S. Food and Drug Administration (FDA), Updated Assessment of The Use of Laparoscopic Power Morcellators to Treat Uterine Fibroids, December 2017; Vilos et al., Journal of obstetrics and gynaecology Canada: JOGC 2015, 37: 157-81).

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy +/- BSO or Bilateral Salpingectomy for Adenomyosis or Fibroids

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ICD-10-CM (circle all that apply): C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C79.82, D06.0, D06.1, D06.7, D06.9, D25.0, D25.1, D25.2, D25.9, N70.01, N70.02, N70.03, N70.11, N70.12, N70.13, N70.91, N70.92, N70.93, N71.1, N71.9, N72, N73.1, N73.4, N73.8, N73.9, N80.0, N80.1, N80.2, N80.3, N80.4, N80.5, N80.6, N80.8, N80.9, N81.2, N81.3, N81.4, N85.00, N85.01, N85.02, N87.0, N87.1, N87.9, N92.1, N92.4, N92.5, N93.0, N93.1, N93.8, N93.9, N95.0, O01.0, O01.1, O01.9, O72.0, O72.1, O72.2, O72.3, R10.10, R10.11, R10.12, R10.13, R10.2, R10.30, R10.31, R10.32, R10.33, R10.811, R10.812, R10.813, R10.814, R10.815, R10.816, R10.817, R10.819, R10.821, R10.822, R10.823, R10.824, R10.825, R10.826, R10.827, R10.829, R10.83, R10.84, R10.9, R19.00, R19.01, R19.02, R19.03, R19.04, R19.05, R19.06, R19.07, R19.09, R93.5, Z14.8, Z15.01, Z15.02, Z15.04, Z15.09, Z15.89, Other _____

ICD-10-PCS (circle all that apply): 0UT20ZZ, 0UT24ZZ, 0UT27ZZ, 0UT28ZZ, 0UT2FZZ, 0UT70ZZ, 0UT74ZZ, 0UT77ZZ, 0UT78ZZ, 0UT7FZZ, 0UT90ZL, 0UT90ZZ, 0UT94ZL, 0UT94ZZ, 0UT97ZL, 0UT97ZZ, 0UT98ZL, 0UT98ZZ, 0UT9FZL, 0UT9FZZ, 0UTC0ZZ, 0UTC4ZZ, 0UTC7ZZ, 0UTC8ZZ, Other _____

CPT® (circle all that apply): 58150, 58152, 58180, 58260, 58262, 58263, 58290, 58291, 58292, 58541, 58542, 58543, 58544, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573, 58575, Other _____

InterQual®

2021, Oct. 2021 Release CP:Procedures

Subset: Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11]

Requested Service: Hysterectomy +/- BSO or Bilateral Salpingectomy for Chronic abdominal or pelvic pain

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:	Date:	
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Chronic abdominal or pelvic pain, unknown etiology

1. Choose all that apply:
   - ☐ A) History and physical examination nondiagnostic for etiology of pain
   - ☐ B) CBC normal
   - ☐ C) Urinalysis or urine culture normal
   - ☐ D) Most recent cervical cytology normal or managed per guidelines [12]
   - ☐ E) Pregnancy excluded by negative human chorionic gonadotropin (HCG) or HCG planned prior to procedure or sterilization by history or patient not sexually active by history [13, 14, 15, 16]
   - ☐ F) Ultrasound within last year nondiagnostic for etiology of pain
   - ☐ G) Other clinical information (add comment)

   • If the number of options selected is 6 and option G not selected, then go to question 2
   • No other options lead to the requested service

2. Testing within last year nondiagnostic for etiology of pain, Choose all that apply:
   - ☐ A) CT or MRI
   - ☐ B) Diagnostic laparoscopy [17]
   - ☐ C) Other clinical information (add comment)

   • If 1 or more options A or B selected and option C not selected, then go to question 3
   • No other options lead to the requested service

EXHIBIT 19

DHHRBMS001066

Chronic abdominal or pelvic pain, unknown etiology (continued...)

3. Treatment within last year, Choose all that apply: [18]
   - ☐ A) NSAIDs ≥ 4 weeks
   - ☐ B) Hormone therapy ≥ 8 weeks [19]
   - ☐ C) GnRH agonist ≥ 8 weeks [20]
   - ☐ D) Antibiotic treatment x1 course
   - ☐ E) Other clinical information (add comment)

   • If 1 or more options A, B, C or D selected and option E not selected, then go to question 4
   • No other options lead to the requested service

4. Continued pain after treatment
   - ☐ A) Yes
   - ☐ B) No

   • If option Yes selected, then the rule is satisfied; you may stop here Ltd 2nd [21, 22, 23]
   • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

3:
Whether to perform prophylactic oophorectomy at the time of hysterectomy done for benign disease in premenopausal women may be considered. There are no published randomized studies to support conservation or prophylactic removal of the ovaries, although observational studies suggest that surgical menopause may increase cardiovascular and overall mortality risk (Orozco et al., The Cochrane database of systematic reviews 2014, 7: CD005638). Generally, bilateral salpingo-oophorectomy (BSO) is recommended for women with BRCA1 or BRCA2 mutations or Lynch syndrome, for postmenopausal women, and for women who have invasive endometrial or ovarian carcinoma (National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: breast and ovarian (Version 3.2019). 2019; National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: colorectal (Version 3.2019). 2019). BSO may also be considered in women who have chronic pelvic pain, pelvic inflammatory disease, or endometriosis, although the risks of surgery should be balanced against the anticipated benefits. Ovarian retention should be considered for premenopausal women who do not have a genetic predisposition to ovarian cancer. Ovarian epithelial carcinoma may originate in cells from the fallopian tube. Therefore, salpingectomy without oophorectomy may be considered in low-risk women who undergo hysterectomy or other pelvic surgery for benign disease, which reduces the risk of ovarian cancer without the development of surgical menopause (American College of Obstetrics and Gynecologists, Obstet Gynecol 2019, 133: e279-e84; Society of Gynecologic Oncology, SGO Clinical Practice Statement: Salpingectomy for Ovarian Cancer Prevention 2013).

4:
Although robotic-assisted hysterectomy is being done, there are few prospective studies comparing robotic assisted to laparoscopic surgery for treating benign disease (ACOG, Obstetrics and Gynecology Committee Opinion No. 628. 2015, 125: 760-7. Reaffirmed 2017; Yu et al., Journal of surgical oncology 2013, 107: 653-8). A Cochrane review, however, demonstrated that robotic-assisted gynecologic surgery required more intraoperative time but reduced hospital stay when compared to laparoscopic surgery. There is no clear evidence to determine which surgery has the lowest complication rate (Liu et al., The Cochrane database of systematic reviews 2014, 12: CD011422). Robotic-assisted surgery can be performed as an outpatient surgery in some patients (Lawrie et al., Cochrane Database Syst Rev 2019, 4: Cd011422).

5:
Total laparoscopic hysterectomy (TLH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are then secured by the endoscopic route. The fundus is then divided and removed through the abdominal wall incisions.

6:
Vaginal hysterectomy offers many advantages to the abdominal or laparoscopic approach including no abdominal incision, less pain, and quicker recovery; if technically feasible, it is the preferred surgical route (American College of Obstetricians and Gynecologists (ACOG), Obstet Gynecol 2017, 129: e155-e9; Sesti et al., Archives of Gynecology and Obstetrics 2014, 290: 485-91). The vaginal technique, however, can be limited in its ability to treat ovarian pathology in large uteri. The preoperative use of GnRH agonists may help shrink large uteri so that a vaginal hysterectomy can be performed (Elzaher et al., European Journal of Obstetrics, Gynecology, and Reproductive Biology 2013, 169: 326-30). Vaginal hysterectomy may be difficult to perform in nulliparous women, obese women, and women with a history of cesarean delivery.

7:
These criteria include the following procedures:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

8:
Laparoscopically assisted vaginal hysterectomy (LAVH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are not secured by the endoscopic route. A vaginal hysterectomy is then performed.

9:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

10:
For cervical cancer stage I-IIA and endometrial cancer stage II, see the "Hysterectomy, Radical" criteria subset.

11:
Supracervical hysterectomy (subtotal hysterectomy) performed as an open or laparoscopic procedure has been thought to preserve sexual, bladder, and bowel function by minimizing disruption of the pelvic floor support and neurovascular supply when compared with total hysterectomy. However, there is inconsistent evidence to show there is an improvement or significant difference in surgical complications, incontinence rate, bladder function, or sexual function when subtotal hysterectomy is compared to total hysterectomy (Lethaby et al., Cochrane Database Syst Rev 2012, 4: CD004993). One 5-year follow-up study of a randomized controlled trial, however, did show higher rates of urinary incontinence and vaginal bleeding in women who had a supracervical hysterectomy compared with those who had a total hysterectomy (Andersen et al., BJOG: An International Journal of Obstetrics and Gynaecology 2015, 122: 851-7). Disadvantages of supracervical hysterectomy include cervical stump complications (e.g., bleeding, pain) and the small risk of developing cervical cancer in the cervical stump (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013). Supracervical hysterectomy may not be appropriate in women who have gynecological cancers, endometrial hyperplasia, or cervical dysplasia (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013).

12:
Cervical cytology should be evaluated according to current screening protocols. Screening intervals and tests used (cervical cytology alone, high-risk human papillomavirus [hrHPV] testing alone, hrHPV and cytology together [co-testing]) will vary based on patient's age and risk factors. If the most recent cervical cytology is documented as normal, no further testing is needed. Any abnormalities detected during cervical cancer screening should be managed according to current guidelines. Management may include repeat testing, observation, surveillance, biopsy, ablation, or excisional treatment based on the identified level of risk for each patient (Redman et al., Eur J Obstet Gynecol Reprod Biol 2021, 256: 57-62; Perkins et al., J Low Genit Tract Dis 2020, 24: 102-31; US Preventative Services Task Force et al., JAMA 2018, 320: 674-86; Wentzensen et al., J Low Genit Tract Dis 2017, 21: 216-22).

13:
Pregnancy and related complications (e.g., ectopic pregnancy, incomplete abortion, inevitable abortion) must be excluded before performing this procedure.

14:
Patients have varying definitions of sexual activity (e.g., number of partners, timing of most recent episode, frequency of sexual activity). Unless the provider can confirm on examination that the patient has never had sexual intercourse, whether a patient is sexually active or not is a matter of clinical judgment.

15:
The documentation should include a history of sterilization (i.e., tubal ligation) without a subsequent pregnancy. These criteria do not include sterilization of a partner or alternate birth control methods (e.g., oral contraceptive pill use, intrauterine device insertion).

16:
Pregnancy testing can be by measurement of either a serum or urine HCG and may be documented in the medical record by either the primary care physician, gynecologist, or surgeon.

17:
Diagnostic laparoscopy may be used in evaluating chronic pelvic pain to identify possible pathologic causes for the pain. Endometriosis is a common cause of pelvic pain and laparoscopy is used to diagnose and treat endometrial lesions. Laparoscopy can also diagnosis other gynecological pathology that may cause chronic pelvic pain such as adhesions and pelvic inflammatory disease (Yunker et al., Obstet Gynecol Surv 2012, 67: 417-25; Won and Abbott, Int J Womens Health 2010, 2: 263-77).

18:
Conservative or less invasive interventions should be tried prior to recommending hysterectomy for the treatment of chronic pelvic pain. Medications such as progesterone and GnRH agonists have shown benefit in decreasing pain, as has a multidisciplinary approach to pain management (Yunker et al., Obstet Gynecol Surv 2012, 67: 417-25). Presacral neurectomy and uterine nerve ablation are techniques that disrupt the nerves that carry pain stimuli to the pelvis. Although several studies have shown significant improvement in pain scores after treatment, the evidence to support these techniques in the treatment of pelvic pain is limited and therefore, these procedures cannot be recommended (Won and Abbott, Int J Womens Health 2010, 2: 263-77; Daniels et al., JAMA 2009; 302(9): 955-961; National Institute for Health and Clinical Excellence (NICE), Interventional procedure overview of laparoscopic uterine nerve ablation (LUNA) for chronic pelvic pain. February 2007, 26).

19:
Although there are few high quality studies, hormone therapy including progestin alone, combined estrogen and progestin, and GnRH agonists have been reported to improve noncyclic chronic pelvic pain (Brown and Farquhar, Cochrane Database Syst Rev 2014: Cd009590).

20:
The GnRH agonists include leuprolide, nafarelin, and goserelin. These compounds mimic the action of GnRH and, thereby, suppress the hormones produced by the ovary that stimulate endometrial growth.

21:
Recommendations are designated as "Limited Evidence" based on one or more of the following:

- Research to date has not demonstrated this intervention's equivalence or superiority to the current standard of care.
- The balance of benefits and harms does not clearly favor this intervention.
- The clinical utility of this intervention has not been clearly established.
- The evidence is mixed, unclear, or of low quality.
- This intervention is not standard of care.
- New technology is still being investigated.

22:
The evaluation of chronic pain can be extensive and finding a cause of the pain may remain elusive. The process of elimination does not ensure that hysterectomy will resolve the pain and pain can persist even after a hysterectomy. Evidence is inconclusive and lacking in controlled trials in regard to the benefit of surgical intervention for chronic pelvic pain (Andrews et al., In: Noncyclic Chronic Pelvic Pain Therapies for Women: Comparative Effectiveness. 2012; Yunker et al., Obstet Gynecol Surv 2012, 67: 417-25). Therefore, requests for hysterectomy for chronic pelvic pain should be reviewed prior to approval.

23:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- BSO or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- BSO or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- BSO or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- BSO or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- BSO or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- BSO or +/- Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy +/- BSO or Bilateral Salpingectomy for Chronic abdominal or pelvic pain

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ICD-10-CM (circle all that apply): C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C79.82, D06.0, D06.1, D06.7, D06.9, D25.0, D25.1, D25.2, D25.9, N70.01, N70.02, N70.03, N70.11, N70.12, N70.13, N70.91, N70.92, N70.93, N71.1, N71.9, N72, N73.1, N73.4, N73.8, N73.9, N80.0, N80.1, N80.2, N80.3, N80.4, N80.5, N80.6, N80.8, N80.9, N81.2, N81.3, N81.4, N85.00, N85.01, N85.02, N87.0, N87.1, N87.9, N92.1, N92.4, N92.5, N93.0, N93.1, N93.8, N93.9, N95.0, O01.0, O01.1, O01.9, O72.0, O72.1, O72.2, O72.3, R10.10, R10.11, R10.12, R10.13, R10.2, R10.30, R10.31, R10.32, R10.33, R10.811, R10.812, R10.813, R10.814, R10.815, R10.816, R10.817, R10.819, R10.821, R10.822, R10.823, R10.824, R10.825, R10.826, R10.827, R10.829, R10.83, R10.84, R10.9, R19.00, R19.01, R19.02, R19.03, R19.04, R19.05, R19.06, R19.07, R19.09, R93.5, Z14.8, Z15.01, Z15.02, Z15.04, Z15.09, Z15.89, Other _____

ICD-10-PCS (circle all that apply): 0UT20ZZ, 0UT24ZZ, 0UT27ZZ, 0UT28ZZ, 0UT2FZZ, 0UT70ZZ, 0UT74ZZ, 0UT77ZZ, 0UT78ZZ, 0UT7FZZ, 0UT90ZL, 0UT90ZZ, 0UT94ZL, 0UT94ZZ, 0UT97ZL, 0UT97ZZ, 0UT98ZL, 0UT98ZZ, 0UT9FZL, 0UT9FZZ, 0UTC0ZZ, 0UTC4ZZ, 0UTC7ZZ, 0UTC8ZZ, Other _____

CPT® (circle all that apply): 58150, 58152, 58180, 58260, 58262, 58263, 58290, 58291, 58292, 58541, 58542, 58543, 58544, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573, 58575, Other _____

InterQual®

2021, Oct. 2021 Release CP:Procedures

Subset: Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11]

Requested Service: Hysterectomy +/- BSO or Bilateral Salpingectomy for CIN 2, CIN 2,3, or CIN 3 or Endometrial hyperplasia (premenopausal)

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:	Date:	
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Choose one of the following options and continue to the appropriate section

- ☐ 10. Cervical intra-epithelial neoplasia (CIN) 2, CIN 2,3, or CIN 3 by biopsy
- ☐ 20. Endometrial hyperplasia with cellular atypia by biopsy or dilatation and curettage (D & C)

☐ 10. Cervical intra-epithelial neoplasia (CIN) 2, CIN 2,3, or CIN 3 by biopsy

1. Excisional procedure performed [12]
   - ☐ A) Yes
   - ☐ B) No

   > • If option Yes selected, then go to question 2
   > • No other options lead to the requested service

2. Continued CIN 2, CIN 2,3, or CIN 3 by endocervical curettage (ECC) or biopsy ≥ 4 months post excisional procedure [13]
   - ☐ A) Yes
   - ☐ B) No

   > • If option Yes selected, then the rule is satisfied; you may stop here [14]
   > • No other options lead to the requested service

☐ 20. Endometrial hyperplasia with cellular atypia by biopsy or dilatation and curettage (D & C)

EXHIBIT 20

DHHRBMS001073

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy +/- BSO or Bilateral Salpingectomy for CIN 2, CIN 2,3, or CIN 3 or Endometrial hyperplasia (premenopausal)

Endometrial hyperplasia with cellular atypia by biopsy or dilatation and curettage (D & C) (continued...)

1. Choose one:
   - ☐ A) Premenopausal woman
   - ☐ B) Postmenopausal woman [15]
   - ☐ C) Other clinical information (add comment)

• If option A selected, then the rule is satisfied; you may stop here [14] • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

3:
Whether to perform prophylactic oophorectomy at the time of hysterectomy done for benign disease in premenopausal women may be considered. There are no published randomized studies to support conservation or prophylactic removal of the ovaries, although observational studies suggest that surgical menopause may increase cardiovascular and overall mortality risk (Orozco et al., The Cochrane database of systematic reviews 2014, 7: CD005638). Generally, bilateral salpingo-oophorectomy (BSO) is recommended for women with BRCA1 or BRCA2 mutations or Lynch syndrome, for postmenopausal women, and for women who have invasive endometrial or ovarian carcinoma (National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: breast and ovarian (Version 3.2019). 2019; National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: colorectal (Version 3.2019). 2019). BSO may also be considered in women who have chronic pelvic pain, pelvic inflammatory disease, or endometriosis, although the risks of surgery should be balanced against the anticipated benefits. Ovarian retention should be considered for premenopausal women who do not have a genetic predisposition to ovarian cancer. Ovarian epithelial carcinoma may originate in cells from the fallopian tube. Therefore, salpingectomy without oophorectomy may be considered in low-risk women who undergo hysterectomy or other pelvic surgery for benign disease, which reduces the risk of ovarian cancer without the development of surgical menopause (American College of Obstetrics and Gynecologists, Obstet Gynecol 2019, 133: e279-e84; Society of Gynecologic Oncology, SGO Clinical Practice Statement: Salpingectomy for Ovarian Cancer Prevention 2013).

4:
Although robotic-assisted hysterectomy is being done, there are few prospective studies comparing robotic assisted to laparoscopic surgery for treating benign disease (ACOG, Obstetrics and Gynecology Committee Opinion No. 628. 2015, 125: 760-7. Reaffirmed 2017; Yu et al., Journal of surgical oncology 2013, 107: 653-8). A Cochrane review, however, demonstrated that robotic-assisted gynecologic surgery required more intraoperative time but reduced hospital stay when compared to laparoscopic surgery. There is no clear evidence to determine which surgery has the lowest complication rate (Liu et al., The Cochrane database of systematic reviews 2014, 12: CD011422). Robotic-assisted surgery can be performed as an outpatient surgery in some patients (Lawrie et al., Cochrane Database Syst Rev 2019, 4: Cd011422).

5:
Total laparoscopic hysterectomy (TLH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are then secured by the endoscopic route. The fundus is then divided and removed through the abdominal wall incisions.

6:
Vaginal hysterectomy offers many advantages to the abdominal or laparoscopic approach including no abdominal incision, less pain, and quicker recovery; if technically feasible, it is the preferred surgical route (American College of Obstetricians and Gynecologists (ACOG), Obstet Gynecol 2017, 129: e155-e9; Sesti et al., Archives of Gynecology and Obstetrics 2014, 290: 485-91). The vaginal technique, however, can be limited in its ability to treat ovarian pathology in large uteri. The preoperative use of GnRH agonists may help shrink large uteri so that a vaginal hysterectomy can be performed (Elzaher et al., European Journal of Obstetrics, Gynecology, and Reproductive Biology 2013, 169: 326-30). Vaginal hysterectomy may be difficult to perform in nulliparous women, obese women, and women with a history of cesarean delivery.

7:
These criteria include the following procedures:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

8:
Laparoscopically assisted vaginal hysterectomy (LAVH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are not secured by the endoscopic route. A vaginal hysterectomy is then performed.

9:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

10:
For cervical cancer stage I-IIA and endometrial cancer stage II, see the "Hysterectomy, Radical" criteria subset.

11:
Supracervical hysterectomy (subtotal hysterectomy) performed as an open or laparoscopic procedure has been thought to preserve sexual, bladder, and bowel function by minimizing disruption of the pelvic floor support and neurovascular supply when compared with total hysterectomy. However, there is inconsistent evidence to show there is an improvement or significant difference in surgical complications, incontinence rate, bladder function, or sexual function when subtotal hysterectomy is compared to total hysterectomy (Lethaby et al., Cochrane Database Syst Rev 2012, 4: CD004993). One 5-year follow-up study of a randomized controlled trial, however, did show higher rates of urinary incontinence and vaginal bleeding in women who had a supracervical hysterectomy compared with those who had a total hysterectomy (Andersen et al., BJOG: An International Journal of Obstetrics and Gynaecology 2015, 122: 851-7). Disadvantages of supracervical hysterectomy include cervical stump complications (e.g., bleeding, pain) and the small risk of developing cervical cancer in the cervical stump (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013). Supracervical hysterectomy may not be appropriate in women who have gynecological cancers, endometrial hyperplasia, or cervical dysplasia (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013).

12:
Excisional procedures include laser conization, cold knife conization, loop electrosurgical excision procedure (LEEP), and loop electrosurgical conization and are performed to obtain a specimen from the transformation zone and endocervical canal for histopathological evaluation. One technique has not been proven to be superior to another (Martin-Hirsch et al., The Cochrane database of systematic reviews 2013, 12: CD001318).

13:
Cervical intra-epithelial neoplasia (CIN) 2, CIN 2,3, or CIN 3 are indications for hysterectomy if conservative excisional surgery fails. Retesting is done approximately 4 months after conservative treatment, as the cervix needs time to heal and continued inflammation can result in abnormal biopsy results. When future childbearing is desired or in younger women with CIN 2, continued conservative surgery may be repeated until the childbearing years end (American College of Obstetricians and Gynecologists, Obstet Gynecol 2013, 122: 1338-67. Reaffirmed 2018; Massad et al., J Low Genit Tract Dis 2013, 17: S1-S27).

14:
I/O Setting:
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

15:
Hysterectomy with removal of both ovaries and fallopian tubes is usually performed in postmenopausal women because the risk for the development of ovarian cancer is higher than for premenopausal women.

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy +/- BSO or Bilateral Salpingectomy for CIN 2, CIN 2,3, or CIN 3 or Endometrial hyperplasia (premenopausal)

ICD-10-CM (circle all that apply): C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C79.82, D06.0, D06.1, D06.7, D06.9, D25.0, D25.1, D25.2, D25.9, N70.01, N70.02, N70.03, N70.11, N70.12, N70.13, N70.91, N70.92, N70.93, N71.1, N71.9, N72, N73.1, N73.4, N73.8, N73.9, N80.0, N80.1, N80.2, N80.3, N80.4, N80.5, N80.6, N80.8, N80.9, N81.2, N81.3, N81.4, N85.00, N85.01, N85.02, N87.0, N87.1, N87.9, N92.1, N92.4, N92.5, N93.0, N93.1, N93.8, N93.9, N95.0, O01.0, O01.1, O01.9, O72.0, O72.1, O72.2, O72.3, R10.10, R10.11, R10.12, R10.13, R10.2, R10.30, R10.31, R10.32, R10.33, R10.811, R10.812, R10.813, R10.814, R10.815, R10.816, R10.817, R10.819, R10.821, R10.822, R10.823, R10.824, R10.825, R10.826, R10.827, R10.829, R10.83, R10.84, R10.9, R19.00, R19.01, R19.02, R19.03, R19.04, R19.05, R19.06, R19.07, R19.09, R93.5, Z14.8, Z15.01, Z15.02, Z15.04, Z15.09, Z15.89, Other _____

ICD-10-PCS (circle all that apply): 0UT20ZZ, 0UT24ZZ, 0UT27ZZ, 0UT28ZZ, 0UT2FZZ, 0UT70ZZ, 0UT74ZZ, 0UT77ZZ, 0UT78ZZ, 0UT7FZZ, 0UT90ZZ, 0UT94ZZ, 0UT97ZZ, 0UT98ZZ, 0UT9FZZ, 0UTC0ZZ, 0UTC4ZZ, 0UTC7ZZ, 0UTC8ZZ, Other _____

CPT® (circle all that apply): 58150, 58152, 58260, 58262, 58263, 58290, 58291, 58292, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573, 58575, Other _____

InterQual®

2021, Oct. 2021 Release CP:Procedures

Subset: Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11]

Requested Service: Hysterectomy +/- BSO or Bilateral Salpingectomy for Gestational Trophoblastic disease

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:	Date:	
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Gestational trophoblastic disease by imaging

1. Choose one: [12, 13, 14]
   - ☐ A) Noninvasive hydatidiform mole by imaging
   - ☐ B) Gestational trophoblastic neoplasia by testing [15]
   - ☐ C) Other clinical information (add comment)

   > • If option B selected, then the rule is satisfied; you may stop here [16]
   > • If option A selected, then go to question 2
   > • No other options lead to the requested service

2. Childbearing desired
   - ☐ A) Yes
   - ☐ B) No

   > • If option No selected, then the rule is satisfied; you may stop here [16]
   > • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

EXHIBIT 21

DHHRBMS001079

Notes:

1:
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2:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

3:
Whether to perform prophylactic oophorectomy at the time of hysterectomy done for benign disease in premenopausal women may be considered. There are no published randomized studies to support conservation or prophylactic removal of the ovaries, although observational studies suggest that surgical menopause may increase cardiovascular and overall mortality risk (Orozco et al., The Cochrane database of systematic reviews 2014, 7: CD005638). Generally, bilateral salpingo-oophorectomy (BSO) is recommended for women with BRCA1 or BRCA2 mutations or Lynch syndrome, for postmenopausal women, and for women who have invasive endometrial or ovarian carcinoma (National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: breast and ovarian (Version 3.2019). 2019; National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: colorectal (Version 3.2019). 2019). BSO may also be considered in women who have chronic pelvic pain, pelvic inflammatory disease, or endometriosis, although the risks of surgery should be balanced against the anticipated benefits. Ovarian retention should be considered for premenopausal women who do not have a genetic predisposition to ovarian cancer. Ovarian epithelial carcinoma may originate in cells from the fallopian tube. Therefore, salpingectomy without oophorectomy may be considered in low-risk women who undergo hysterectomy or other pelvic surgery for benign disease, which reduces the risk of ovarian cancer without the development of surgical menopause (American College of Obstetrics and Gynecologists, Obstet Gynecol 2019, 133: e279-e84; Society of Gynecologic Oncology, SGO Clinical Practice Statement: Salpingectomy for Ovarian Cancer Prevention 2013).

4:
Although robotic-assisted hysterectomy is being done, there are few prospective studies comparing robotic assisted to laparoscopic surgery for treating benign disease (ACOG, Obstetrics and Gynecology Committee Opinion No. 628. 2015, 125: 760-7. Reaffirmed 2017; Yu et al., Journal of surgical oncology 2013, 107: 653-8). A Cochrane review, however, demonstrated that robotic-assisted gynecologic surgery required more intraoperative time but reduced hospital stay when compared to laparoscopic surgery. There is no clear evidence to determine which surgery has the lowest complication rate (Liu et al., The Cochrane database of systematic reviews 2014, 12: CD011422). Robotic-assisted surgery can be performed as an outpatient surgery in some patients (Lawrie et al., Cochrane Database Syst Rev 2019, 4: Cd011422).

5:
Total laparoscopic hysterectomy (TLH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are then secured by the endoscopic route. The fundus is then divided and removed through the abdominal wall incisions.

6:
Vaginal hysterectomy offers many advantages to the abdominal or laparoscopic approach including no abdominal incision, less pain, and quicker recovery; if technically feasible, it is the preferred surgical route (American College of Obstetricians and Gynecologists (ACOG), Obstet Gynecol 2017, 129: e155-e9; Sesti et al., Archives of Gynecology and Obstetrics 2014, 290: 485-91). The vaginal technique, however, can be limited in its ability to treat ovarian pathology in large uteri. The preoperative use of GnRH agonists may help shrink large uteri so that a vaginal hysterectomy can be performed (Elzaher et al., European Journal of Obstetrics, Gynecology, and Reproductive Biology 2013, 169: 326-30). Vaginal hysterectomy may be difficult to perform in nulliparous women, obese women, and women with a history of cesarean delivery.

7:
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Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

8:
Laparoscopically assisted vaginal hysterectomy (LAVH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are not secured by the endoscopic route. A vaginal hysterectomy is then performed.

9:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

10:
For cervical cancer stage I-IIA and endometrial cancer stage II, see the "Hysterectomy, Radical" criteria subset.

11:
Supracervical hysterectomy (subtotal hysterectomy) performed as an open or laparoscopic procedure has been thought to preserve sexual, bladder, and bowel function by minimizing disruption of the pelvic floor support and neurovascular supply when compared with total hysterectomy. However, there is inconsistent evidence to show there is an improvement or significant difference in surgical complications, incontinence rate, bladder function, or sexual function when subtotal hysterectomy is compared to total hysterectomy (Lethaby et al., Cochrane Database Syst Rev 2012, 4: CD004993). One 5-year follow-up study of a randomized controlled trial, however, did show higher rates of urinary incontinence and vaginal bleeding in women who had a supracervical hysterectomy compared with those who had a total hysterectomy (Andersen et al., BJOG: An International Journal of Obstetrics and Gynaecology 2015, 122: 851-7). Disadvantages of supracervical hysterectomy include cervical stump complications (e.g., bleeding, pain) and the small risk of developing cervical cancer in the cervical stump (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013). Supracervical hysterectomy may not be appropriate in women who have gynecological cancers, endometrial hyperplasia, or cervical dysplasia (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013).

12:
The primary treatment option for hydatidiform mole is dilatation and curettage (D & C) for women who wish to preserve fertility. Hysterectomy is an alternative for older women or for those who do not wish to maintain fertility (Abu-Rustum et al., J Natl Compr Canc Netw 2019, 17: 1374-91). Post treatment HCG monitoring is indicated until levels return to normal. Postmolar gestational trophoblastic neoplasm is primarily diagnosed by HCG monitoring. Repeat D & C or hysterectomy can be considered (Abu-Rustum et al., J Natl Compr Canc Netw 2019, 17: 1374-91).

13:
Elevated HCG is present in all forms of gestational trophoblastic disease. Imaging, primarily transvaginal or abdominal ultrasound, is indicated during the initial diagnosis, staging, and risk assessment (Dudiak et al., J Am Coll Radiol 2019, 16: S348-s63).

14:
Staging and prognosis are combined in the international Federation of Gynecology and Obstetrics staging system. This system takes into account anatomic staging along with patient age, type of antecedent pregnancy, interval from gestational event, HCG, number and site of metastases, largest tumor, and previous chemotherapy to further develop a treatment plan (Abu-Rustum et al., J Natl Compr Canc Netw 2019, 17: 1374-91; Dudiak et al., J Am Coll Radiol 2019, 16: S348-s63). Staging is based on the location of the tumor and extent of metastasis: a stage I tumor is confined to the uterus, stage II involves other genital structures (e.g., ovary, tube, vagina, broad ligaments), stage III involves lung metastasis, and stage VI includes all other distant metastases (Abu-Rustum et al., J Natl Compr Canc Netw 2019, 17: 1374-91).

15:
While hydatidiform mole and choriocarcinoma typically develop from villous trophoblast, intermediate trophoblastic tumors (e.g., epithelioid and placental site trophoblastic tumors) may develop from extravillous trophoblast. These are relatively chemotherapy resistant; therefore, hysterectomy with lymph node dissection is preferred for localized disease (Abu-Rustum et al., J Natl Compr Canc Netw 2019, 17: 1374-91).

16:
I/O Setting:
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy +/- BSO or Bilateral Salpingectomy for Gestational Trophoblastic disease

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ICD-10-CM (circle all that apply): C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C79.82, D06.0, D06.1, D06.7, D06.9, D25.0, D25.1, D25.2, D25.9, N70.01, N70.02, N70.03, N70.11, N70.12, N70.13, N70.91, N70.92, N70.93, N71.1, N71.9, N72, N73.1, N73.4, N73.8, N73.9, N80.0, N80.1, N80.2, N80.3, N80.4, N80.5, N80.6, N80.8, N80.9, N81.2, N81.3, N81.4, N85.00, N85.01, N85.02, N87.0, N87.1, N87.9, N92.1, N92.4, N92.5, N93.0, N93.1, N93.8, N93.9, N95.0, O01.0, O01.1, O01.9, O72.0, O72.1, O72.2, O72.3, R10.10, R10.11, R10.12, R10.13, R10.2, R10.30, R10.31, R10.32, R10.33, R10.811, R10.812, R10.813, R10.814, R10.815, R10.816, R10.817, R10.819, R10.821, R10.822, R10.823, R10.824, R10.825, R10.826, R10.827, R10.829, R10.83, R10.84, R10.9, R19.00, R19.01, R19.02, R19.03, R19.04, R19.05, R19.06, R19.07, R19.09, R93.5, Z14.8, Z15.01, Z15.02, Z15.04, Z15.09, Z15.89, Other _____

ICD-10-PCS (circle all that apply): 0UT20ZZ, 0UT24ZZ, 0UT70ZZ, 0UT74ZZ, 0UT90ZL, 0UT90ZZ, 0UT94ZL, 0UT94ZZ, 0UTC0ZZ, 0UTC4ZZ, 0UTF0ZZ, 0UTF4ZZ, Other _____

CPT® (circle all that apply): 58150, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573, Other _____

InterQual®

2021, Oct. 2021 Release CP:Procedures

Subset: Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11]

Requested Service: Hysterectomy +/- BSO or Bilateral Salpingectomy for Postpartum uterine bleeding

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Postpartum uterine bleeding ≤ 24 hours post delivery (urgent)

1. Choose all that apply: [12]
   - ☐ A) Vaginal or vulvar or cervical laceration excluded by physical examination
   - ☐ B) Uterine rupture excluded by physical examination or ultrasound [13]
   - ☐ C) Failure of vigorous uterine massage to control bleeding
   - ☐ D) Unsuccessful manual extraction of the placenta or manual extraction not indicated
   - ☐ E) Dilatation and curettage (D&C) performed
   - ☐ F) Unsuccessful balloon tamponade
   - ☐ G) Other clinical information (add comment)

   • If the number of options selected is 6 and option G not selected, then go to question 2
   • No other options lead to the requested service

2. Choose all that apply: [14]
   - ☐ A) Pitocin
   - ☐ B) Methergine
   - ☐ C) Prostaglandin
   - ☐ D) Other clinical information (add comment)

   • If 2 or more options A, B or C selected and option D not selected, then go to question 3
   • No other options lead to the requested service

EXHIBIT 22

DHHRBMS001084

Postpartum uterine bleeding ≤ 24 hours post delivery (urgent) (continued...)

3. Continued bleeding after treatment
   - ☐ A) Yes
   - ☐ B) No

> • If option Yes selected, then the rule is satisfied; you may stop here (15)
> • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

3:
Whether to perform prophylactic oophorectomy at the time of hysterectomy done for benign disease in premenopausal women may be considered. There are no published randomized studies to support conservation or prophylactic removal of the ovaries, although observational studies suggest that surgical menopause may increase cardiovascular and overall mortality risk (Orozco et al., The Cochrane database of systematic reviews 2014, 7: CD005638). Generally, bilateral salpingo-oophorectomy (BSO) is recommended for women with BRCA1 or BRCA2 mutations or Lynch syndrome, for postmenopausal women, and for women who have invasive endometrial or ovarian carcinoma (National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: breast and ovarian (Version 3.2019). 2019; National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: colorectal (Version 3.2019). 2019). BSO may also be considered in women who have chronic pelvic pain, pelvic inflammatory disease, or endometriosis, although the risks of surgery should be balanced against the anticipated benefits. Ovarian retention should be considered for premenopausal women who do not have a genetic predisposition to ovarian cancer. Ovarian epithelial carcinoma may originate in cells from the fallopian tube. Therefore, salpingectomy without oophorectomy may be considered in low-risk women who undergo hysterectomy or other pelvic surgery for benign disease, which reduces the risk of ovarian cancer without the development of surgical menopause (American College of Obstetrics and Gynecologists, Obstet Gynecol 2019, 133: e279-e84; Society of Gynecologic Oncology, SGO Clinical Practice Statement: Salpingectomy for Ovarian Cancer Prevention 2013).

4:
Although robotic-assisted hysterectomy is being done, there are few prospective studies comparing robotic assisted to laparoscopic surgery for treating benign disease (ACOG, Obstetrics and Gynecology Committee Opinion No. 628. 2015, 125: 760-7. Reaffirmed 2017; Yu et al., Journal of surgical oncology 2013, 107: 653-8). A Cochrane review, however, demonstrated that robotic-assisted gynecologic surgery required more intraoperative time but reduced hospital stay when compared to laparoscopic surgery. There is no clear evidence to determine which surgery has the lowest complication rate (Liu et al., The Cochrane database of systematic reviews 2014, 12: CD011422). Robotic-assisted surgery can be performed as an outpatient surgery in some patients (Lawrie et al., Cochrane Database Syst Rev 2019, 4: Cd011422).

5:
Total laparoscopic hysterectomy (TLH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are then secured by the endoscopic route. The fundus is then divided and removed through the abdominal wall incisions.

6:
Vaginal hysterectomy offers many advantages to the abdominal or laparoscopic approach including no abdominal incision, less pain, and quicker recovery; if technically feasible, it is the preferred surgical route (American College of Obstetricians and Gynecologists (ACOG), Obstet Gynecol 2017, 129: e155-e9; Sesti et al., Archives of Gynecology and Obstetrics 2014, 290: 485-91). The vaginal technique, however, can be limited in its ability to treat ovarian pathology in large uteri. The preoperative use of GnRH agonists may help shrink large uteri so that a vaginal hysterectomy can be performed (Elzaher et al., European Journal of Obstetrics, Gynecology, and Reproductive Biology 2013, 169: 326-30). Vaginal hysterectomy may be difficult to perform in nulliparous women, obese women, and women with a history of cesarean delivery.

7:
These criteria include the following procedures:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

8:
Laparoscopically assisted vaginal hysterectomy (LAVH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are not secured by the endoscopic route. A vaginal hysterectomy is then performed.

9:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

10:
For cervical cancer stage I-IIA and endometrial cancer stage II, see the "Hysterectomy, Radical" criteria subset.

11:
Supracervical hysterectomy (subtotal hysterectomy) performed as an open or laparoscopic procedure has been thought to preserve sexual, bladder, and bowel function by minimizing disruption of the pelvic floor support and neurovascular supply when compared with total hysterectomy. However, there is inconsistent evidence to show there is an improvement or significant difference in surgical complications, incontinence rate, bladder function, or sexual function when subtotal hysterectomy is compared to total hysterectomy (Lethaby et al., Cochrane Database Syst Rev 2012, 4: CD004993). One 5-year follow-up study of a randomized controlled trial, however, did show higher rates of urinary incontinence and vaginal bleeding in women who had a supracervical hysterectomy compared with those who had a total hysterectomy (Andersen et al., BJOG: An International Journal of Obstetrics and Gynaecology 2015, 122: 851-7). Disadvantages of supracervical hysterectomy include cervical stump complications (e.g., bleeding, pain) and the small risk of developing cervical cancer in the cervical stump (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013). Supracervical hysterectomy may not be appropriate in women who have gynecological cancers, endometrial hyperplasia, or cervical dysplasia (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013).

12:
Uterine massage, manual extraction of the placenta, uterine curettage, repair of any genital lacerations, and balloon tamponade are all techniques that are used to manage postpartum hemorrhage (American College of Obstetricians and Gynecologists, Obstet Gynecol 2017, 130: e168-e86. Reaffirmed 2019). Additional interventions that may be considered if the patient is stable include arterial ligation or embolization (American College of Obstetricians and Gynecologists, Obstet Gynecol 2017, 130: e168-e86. Reaffirmed 2019; Abdul-Kadir et al., Transfusion 2014, 54: 1756-68).

13:
Uterine rupture is defined as a disruption in the continuity of the uterine wall and the overlying visceral peritoneum. Uterine rupture may be associated with clinically significant uterine bleeding, fetal distress, or protrusion of the fetus or placenta into the abdominal cavity and results in a need for urgent cesarean delivery, uterine repair, or hysterectomy.

14:
Uterine atony is the most common cause of postpartum hemorrhage. It can be managed in most cases with intravenous, intramyometrial, intramuscular, or rectal uterotonic medications (e.g., pitocin, methergine, prostaglandin) which induce contractions and increase uterine muscle tone. The antifibrinolytic agent tranexamic acid may be another pharmacological option (American College of Obstetricians and Gynecologists, Obstet Gynecol 2017, 130: e168-e86. Reaffirmed 2019; Abdul-Kadir et al., Transfusion 2014, 54: 1756-68). Recombinant human factor VIIa may be effective in treating postpartum hemorrhage that does not improve with uterotonics (Lavigne-Lissalde et al., Journal of thrombosis and haemostasis: JTH 2015, 13: 520-9). It remains unclear as to the most effective fertility sparing treatment for postpartum hemorrhage that does not respond to uterotonics (American College of Obstetricians and Gynecologists, Obstet Gynecol 2017, 130: e168-e86. Reaffirmed 2019; Doumouchtsis et al., BJOG: an international journal of obstetrics and gynaecology 2014, 121: 382-8; Mousa et al., The Cochrane database of systematic reviews 2014, 2: CD003249).

15:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy +/- BSO or Bilateral Salpingectomy for Postpartum uterine bleeding

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ICD-10-CM (circle all that apply): C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C79.82, D06.0, D06.1, D06.7, D06.9, D25.0, D25.1, D25.2, D25.9, N70.01, N70.02, N70.03, N70.11, N70.12, N70.13, N70.91, N70.92, N70.93, N71.1, N71.9, N72, N73.1, N73.4, N73.8, N73.9, N80.0, N80.1, N80.2, N80.3, N80.4, N80.5, N80.6, N80.8, N80.9, N81.2, N81.3, N81.4, N85.00, N85.01, N85.02, N87.0, N87.1, N87.9, N92.1, N92.4, N92.5, N93.0, N93.1, N93.8, N93.9, N95.0, O01.0, O01.1, O01.9, O72.0, O72.1, O72.2, O72.3, R10.10, R10.11, R10.12, R10.13, R10.2, R10.30, R10.31, R10.32, R10.33, R10.811, R10.812, R10.813, R10.814, R10.815, R10.816, R10.817, R10.819, R10.821, R10.822, R10.823, R10.824, R10.825, R10.826, R10.827, R10.829, R10.83, R10.84, R10.9, R19.00, R19.01, R19.02, R19.03, R19.04, R19.05, R19.06, R19.07, R19.09, R93.5, Z14.8, Z15.01, Z15.02, Z15.04, Z15.09, Z15.89, Other _____

ICD-10-PCS (circle all that apply): 0UT20ZZ, 0UT70ZZ, 0UT90ZL, 0UT90ZZ, 0UTC0ZZ, Other _____

CPT® (circle all that apply): 58150, 58152, 58180, Other _____

InterQual®

2021, Oct. 2021 Release CP:Procedures

Subset: Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11]

Requested Service: Hysterectomy +/- BSO or Bilateral Salpingectomy for Uterine prolapse

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:	Date:	
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Uterine prolapse

1. Uterine prolapse by physical examination, Choose one: [12]
   - ☐ A) Stage II or Grade 2
   - ☐ B) Stage III or Grade 3
   - ☐ C) Stage IV or Grade 4
   - ☐ D) Other clinical information (add comment)

   • If option A, B or C selected, then go to question 2
   • No other options lead to the requested service

2. Choose all that apply: [13]
   - ☐ A) Pelvic pressure by history
   - ☐ B) Pelvic pain by history
   - ☐ C) Stress incontinence by history
   - ☐ D) Ulceration with bleeding or spotting by physical examination
   - ☐ E) Vaginal splinting [14]
   - ☐ F) Sexual dysfunction or dyspareunia or coital incontinence
   - ☐ G) Other clinical information (add comment)

   • If 1 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
   • No other options lead to the requested service

EXHIBIT 23

DHHRBMS001090

Uterine prolapse (continued...)

3. Choose all that apply:
   - ☐ A) Most recent cervical cytology normal or managed per guidelines [15]
   - ☐ B) Pregnancy excluded by negative HCG or HCG planned prior to procedure or sterilization by history or patient not sexually active by history [16, 17, 18, 19]
   - ☐ C) Other clinical information (add comment)

• If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here [20]
• No other options lead to the requested service

Reference

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2nd - Secondary review required. Criteria cannot be met.

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Notes:

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3:
Whether to perform prophylactic oophorectomy at the time of hysterectomy done for benign disease in premenopausal women may be considered. There are no published randomized studies to support conservation or prophylactic removal of the ovaries, although observational studies suggest that surgical menopause may increase cardiovascular and overall mortality risk (Orozco et al., The Cochrane database of systematic reviews 2014, 7: CD005638). Generally, bilateral salpingo-oophorectomy (BSO) is recommended for women with BRCA1 or BRCA2 mutations or Lynch syndrome, for postmenopausal women, and for women who have invasive endometrial or ovarian carcinoma (National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: breast and ovarian (Version 3.2019). 2019; National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: colorectal (Version 3.2019). 2019). BSO may also be considered in women who have chronic pelvic pain, pelvic inflammatory disease, or endometriosis, although the risks of surgery should be balanced against the anticipated benefits. Ovarian retention should be considered for premenopausal women who do not have a genetic predisposition to ovarian cancer. Ovarian epithelial carcinoma may originate in cells from the fallopian tube. Therefore, salpingectomy without oophorectomy may be considered in low-risk women who undergo hysterectomy or other pelvic surgery for benign disease, which reduces the risk of ovarian cancer without the development of surgical menopause (American College of Obstetrics and Gynecologists, Obstet Gynecol 2019, 133: e279-e84; Society of Gynecologic Oncology, SGO Clinical Practice Statement: Salpingectomy for Ovarian Cancer Prevention 2013).

4:
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5:
Total laparoscopic hysterectomy (TLH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are then secured by the endoscopic route. The fundus is then divided and removed through the abdominal wall incisions.

6:
Vaginal hysterectomy offers many advantages to the abdominal or laparoscopic approach including no abdominal incision, less pain, and quicker recovery; if technically feasible, it is the preferred surgical route (American College of Obstetricians and Gynecologists (ACOG), Obstet Gynecol 2017, 129: e155-e9; Sesti et al., Archives of Gynecology and Obstetrics 2014, 290: 485-91). The vaginal technique, however, can be limited in its ability to treat ovarian pathology in large uteri. The preoperative use of GnRH agonists may help shrink large uteri so that a vaginal hysterectomy can be performed (Elzaher et al., European Journal of Obstetrics, Gynecology, and Reproductive Biology 2013, 169: 326-30). Vaginal hysterectomy may be difficult to perform in nulliparous women, obese women, and women with a history of cesarean delivery.

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These criteria include the following procedures:
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Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

8:
Laparoscopically assisted vaginal hysterectomy (LAVH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are not secured by the endoscopic route. A vaginal hysterectomy is then performed.

9:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
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Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

10:
For cervical cancer stage I-IIA and endometrial cancer stage II, see the "Hysterectomy, Radical" criteria subset.

11:
Supracervical hysterectomy (subtotal hysterectomy) performed as an open or laparoscopic procedure has been thought to preserve sexual, bladder, and bowel function by minimizing disruption of the pelvic floor support and neurovascular supply when compared with total hysterectomy. However, there is inconsistent evidence to show there is an improvement or significant difference in surgical complications, incontinence rate, bladder function, or sexual function when subtotal hysterectomy is compared to total hysterectomy (Lethaby et al., Cochrane Database Syst Rev 2012, 4: CD004993). One 5-year follow-up study of a randomized controlled trial, however, did show higher rates of urinary incontinence and vaginal bleeding in women who had a supracervical hysterectomy compared with those who had a total hysterectomy (Andersen et al., BJOG: An International Journal of Obstetrics and Gynaecology 2015, 122: 851-7). Disadvantages of supracervical hysterectomy include cervical stump complications (e.g., bleeding, pain) and the small risk of developing cervical cancer in the cervical stump (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013). Supracervical hysterectomy may not be appropriate in women who have gynecological cancers, endometrial hyperplasia, or cervical dysplasia (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013).

12:
There are multiple methods of measuring or evaluating pelvic organ prolapse. Two commonly used systems are the Baden-Walker system (grades 0 to 4) and pelvic organ prolapse-quantification (pelvic organ prolapse-Q stages 0 to IV). These systems measure the most distal portion of the prolapse during straining or a Valsalva maneuver. The Braden-Walker method is a clinical measurement of the 3 pelvic compartments. The pelvic organ prolapse-Q system is more complex and involves taking several measurements (American College Obstetricians and Gynecologists (ACOG), Obstet Gynecol 2019, 134: e126-e42).
Braden-Walker system:
Grade 0 - Normal position, no prolapse
Grade 1 - Halfway decent to the hymen
Grade 2 - Descent to the hymen
Grade 3 - Descent halfway past the hymen
Grade 4 - Maximal possible descent for each site
Pelvic organ prolapse-quantification system:
Stage 0 - No prolapse
Stage I - > 1 cm above the hymen
Stage II - ≤ 1 cm proximal or distal to the plane of the hymen
Stage III - > 1 cm below the plane of the hymen but no further than 2 cm less than the total vaginal length
Stage IV - Complete eversion of the lower genital tract

13:
Treatment is only needed if the prolapse is causing symptoms related to bulging, pressure, sexual dysfunction, lower urinary tract dysfunction, or dysfunctional defecation. Symptoms are experienced by most women when the pelvic organ prolapse is at stage II, grade 2, or higher. Symptoms may be experienced by women who have stage I or grade 1 prolapse but are less common and surgery is rarely needed for that lower stage or grade (Committee on Practice Bulletins-Gynecology, Obstet Gynecol 2017, 130: e234-e50).

14:
Def: With vaginal splinting, the woman must place at least one finger in the vagina to assist a bowel movement.

15:
Cervical cytology should be evaluated according to current screening protocols. Screening intervals and tests used (cervical cytology alone, high-risk human papillomavirus [hrHPV] testing alone, hrHPV and cytology together [co-testing]) will vary based on patient's age and risk factors. If the most recent cervical cytology is documented as normal, no further testing is needed. Any abnormalities detected during cervical cancer screening should be managed according to current guidelines. Management may include repeat testing, observation, surveillance, biopsy, ablation, or excisional treatment based on the identified level of risk for each patient (Redman et al., Eur J Obstet Gynecol Reprod Biol 2021, 256: 57-62; Perkins et al., J Low Genit Tract Dis 2020, 24: 102-31; US Preventative Services Task Force et al., JAMA 2018, 320: 674-86; Wentzensen et al., J Low Genit Tract Dis 2017, 21: 216-22).

16:
Pregnancy and related complications (e.g., ectopic pregnancy, incomplete abortion, inevitable abortion) must be excluded before performing this procedure.

17:
Pregnancy testing can be performed by measurement of either a serum or urine HCG and may be documented in the medical record by either the PCP, a gynecologist, or a surgeon.

18:
The documentation should include a history of sterilization (i.e., tubal ligation) without a subsequent pregnancy. These criteria do not include sterilization of a partner or alternate birth control methods (e.g., oral contraceptive pill use, intrauterine device insertion).

19:
Patients have varying definitions of sexual activity (e.g., number of partners, timing of most recent episode, frequency of sexual activity). Unless the provider can confirm on examination that the patient has never had sexual intercourse, whether a patient is sexually active or not is a matter of clinical judgment.

20:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy +/- BSO or Bilateral Salpingectomy for Uterine prolapse

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ICD-10-CM (circle all that apply): C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C79.82, D06.0, D06.1, D06.7, D06.9, D25.0, D25.1, D25.2, D25.9, N70.01, N70.02, N70.03, N70.11, N70.12, N70.13, N70.91, N70.92, N70.93, N71.1, N71.9, N72, N73.1, N73.4, N73.8, N73.9, N80.0, N80.1, N80.2, N80.3, N80.4, N80.5, N80.6, N80.8, N80.9, N81.2, N81.3, N81.4, N85.00, N85.01, N85.02, N87.0, N87.1, N87.9, N92.1, N92.4, N92.5, N93.0, N93.1, N93.8, N93.9, N95.0, O01.0, O01.1, O01.9, O72.0, O72.1, O72.2, O72.3, R10.10, R10.11, R10.12, R10.13, R10.2, R10.30, R10.31, R10.32, R10.33, R10.811, R10.812, R10.813, R10.814, R10.815, R10.816, R10.817, R10.819, R10.821, R10.822, R10.823, R10.824, R10.825, R10.826, R10.827, R10.829, R10.83, R10.84, R10.9, R19.00, R19.01, R19.02, R19.03, R19.04, R19.05, R19.06, R19.07, R19.09, R93.5, Z14.8, Z15.01, Z15.02, Z15.04, Z15.09, Z15.89, Other _____

ICD-10-PCS (circle all that apply): 0UT20ZZ, 0UT24ZZ, 0UT27ZZ, 0UT28ZZ, 0UT2FZZ, 0UT70ZZ, 0UT74ZZ, 0UT77ZZ, 0UT78ZZ, 0UT7FZZ, 0UT90ZL, 0UT90ZZ, 0UT94ZL, 0UT94ZZ, 0UT97ZL, 0UT97ZZ, 0UT98ZL, 0UT98ZZ, 0UT9FZL, 0UT9FZZ, 0UTC0ZZ, 0UTC4ZZ, 0UTC7ZZ, 0UTC8ZZ, 0UTF0ZZ, 0UTF4ZZ, 0UTF7ZZ, 0UTF8ZZ, Other _____

CPT® (circle all that apply): 58180, 58260, 58262, 58263, 58270, 58290, 58291, 58292, 58294, 58541, 58542, 58543, 58544, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573, Other _____

InterQual®

2021, Oct. 2021 Release CP:Procedures

Subset: Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11]

Requested Service: Hysterectomy +/- BSO or Bilateral Salpingectomy for Pelvic inflammatory disease (PID) or Tubo-ovarian abscess (TOA)
Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:	Date:	
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Choose one of the following options and continue to the appropriate section

- ☐ 10. Chronic pelvic inflammatory disease (PID)
- ☐ 20. Tubo-ovarian abscess (TOA) by imaging

☐ 10. Chronic pelvic inflammatory disease (PID)

1. Choose all that apply:
   - ☐ A) Pelvic pain
   - ☐ B) Acute pelvic inflammatory disease (PID) ≥ 2 episodes by history and physical examination
   - ☐ C) Infection documented ≥ 1 episode by positive culture
   - ☐ D) Most recent cervical cytology normal or managed per guidelines [12]
   - ☐ E) Human chorionic gonadotropin (HCG) negative or HCG planned prior to procedure [13, 14]
   - ☐ F) Other clinical information (add comment)

> • If the number of options selected is 5 and option F not selected, then the rule is satisfied; you may stop here [15]
>
> • No other options lead to the requested service

☐ 20. Tubo-ovarian abscess (TOA) by imaging

EXHIBIT 24

DHHRBMS001097

Tubo-ovarian abscess (TOA) by imaging (continued...)

1. Ectopic pregnancy excluded by negative HCG [14]
   - ☐ A) Yes
   - ☐ B) No

   • If option Yes selected, then go to question 2
   • No other options lead to the requested service

2. Choose all that apply:
   - ☐ A) Pelvic pain
   - ☐ B) Abdominal tenderness
   - ☐ C) Persistent adnexal mass
   - ☐ D) Temperature > 100.4 F (38.0 C)
   - ☐ E) WBC > normal
   - ☐ F) Other clinical information (add comment)

   • If 1 or more options A, B, C, D or E selected and option F not selected, then go to question 3
   • No other options lead to the requested service

3. Worsening symptoms during IV antibiotic treatment [16]
   - ☐ A) Yes
   - ☐ B) No

   • If option Yes selected, then the rule is satisfied; you may stop here [15]
   • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

3:
Whether to perform prophylactic oophorectomy at the time of hysterectomy done for benign disease in premenopausal women may be considered. There are no published randomized studies to support conservation or prophylactic removal of the ovaries, although observational studies suggest that surgical menopause may increase cardiovascular and overall mortality risk (Orozco et al., The Cochrane database of systematic reviews 2014, 7: CD005638). Generally, bilateral salpingo-oophorectomy (BSO) is recommended for women with BRCA1 or BRCA2 mutations or Lynch syndrome, for postmenopausal women, and for women who have invasive endometrial or ovarian carcinoma (National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: breast and ovarian (Version 3.2019). 2019; National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: colorectal (Version 3.2019). 2019). BSO may also be considered in women who have chronic pelvic pain, pelvic inflammatory disease, or endometriosis, although the risks of surgery should be balanced against the anticipated benefits. Ovarian retention should be considered for premenopausal women who do not have a genetic predisposition to ovarian cancer. Ovarian epithelial carcinoma may originate in cells from the fallopian tube. Therefore, salpingectomy without oophorectomy may be considered in low-risk women who undergo hysterectomy or other pelvic surgery for benign disease, which reduces the risk of ovarian cancer without the development of surgical menopause (American College of Obstetrics and Gynecologists, Obstet Gynecol 2019, 133: e279-e84; Society of Gynecologic Oncology, SGO Clinical Practice Statement: Salpingectomy for Ovarian Cancer Prevention 2013).

4:
Although robotic-assisted hysterectomy is being done, there are few prospective studies comparing robotic assisted to laparoscopic surgery for treating benign disease (ACOG, Obstetrics and Gynecology Committee Opinion No. 628. 2015, 125: 760-7. Reaffirmed 2017; Yu et al., Journal of surgical oncology 2013, 107: 653-8). A Cochrane review, however, demonstrated that robotic-assisted gynecologic surgery required more intraoperative time but reduced hospital stay when compared to laparoscopic surgery. There is no clear evidence to determine which surgery has the lowest complication rate (Liu et al., The Cochrane database of systematic reviews 2014, 12: CD011422). Robotic-assisted surgery can be performed as an outpatient surgery in some patients (Lawrie et al., Cochrane Database Syst Rev 2019, 4: Cd011422).

5:
Total laparoscopic hysterectomy (TLH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are then secured by the endoscopic route. The fundus is then divided and removed through the abdominal wall incisions.

6:
Vaginal hysterectomy offers many advantages to the abdominal or laparoscopic approach including no abdominal incision, less pain, and quicker recovery; if technically feasible, it is the preferred surgical route (American College of Obstetricians and Gynecologists (ACOG), Obstet Gynecol 2017, 129: e155-e9; Sesti et al., Archives of Gynecology and Obstetrics 2014, 290: 485-91). The vaginal technique, however, can be limited in its ability to treat ovarian pathology in large uteri. The preoperative use of GnRH agonists may help shrink large uteri so that a vaginal hysterectomy can be performed (Elzaher et al., European Journal of Obstetrics, Gynecology, and Reproductive Biology 2013, 169: 326-30). Vaginal hysterectomy may be difficult to perform in nulliparous women, obese women, and women with a history of cesarean delivery.

7:
These criteria include the following procedures:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

8:
Laparoscopically assisted vaginal hysterectomy (LAVH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are not secured by the endoscopic route. A vaginal hysterectomy is then performed.

9:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

10:
For cervical cancer stage I-IIA and endometrial cancer stage II, see the "Hysterectomy, Radical" criteria subset.

11:
Supracervical hysterectomy (subtotal hysterectomy) performed as an open or laparoscopic procedure has been thought to preserve sexual, bladder, and bowel function by minimizing disruption of the pelvic floor support and neurovascular supply when compared with total hysterectomy. However, there is inconsistent evidence to show there is an improvement or significant difference in surgical complications, incontinence rate, bladder function, or sexual function when subtotal hysterectomy is compared to total hysterectomy (Lethaby et al., Cochrane Database Syst Rev 2012, 4: CD004993). One 5-year follow-up study of a randomized controlled trial, however, did show higher rates of urinary incontinence and vaginal bleeding in women who had a supracervical hysterectomy compared with those who had a total hysterectomy (Andersen et al., BJOG: An International Journal of Obstetrics and Gynaecology 2015, 122: 851-7). Disadvantages of supracervical hysterectomy include cervical stump complications (e.g., bleeding, pain) and the small risk of developing cervical cancer in the cervical stump (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013). Supracervical hysterectomy may not be appropriate in women who have gynecological cancers, endometrial hyperplasia, or cervical dysplasia (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013).

12:
Cervical cytology should be evaluated according to current screening protocols. Screening intervals and tests used (cervical cytology alone, high-risk human papillomavirus [hrHPV] testing alone, hrHPV and cytology together [co-testing]) will vary based on patient's age and risk factors. If the most recent cervical cytology is documented as normal, no further testing is needed. Any abnormalities detected during cervical cancer screening should be managed according to current guidelines. Management may include repeat testing, observation, surveillance, biopsy, ablation, or excisional treatment based on the identified level of risk for each patient (Redman et al., Eur J Obstet Gynecol Reprod Biol 2021, 256: 57-62; Perkins et al., J Low Genit Tract Dis 2020, 24: 102-31; US Preventative Services Task Force et al., JAMA 2018, 320: 674-86; Wentzensen et al., J Low Genit Tract Dis 2017, 21: 216-22).

13:
Pregnancy and related complications (e.g., ectopic pregnancy, incomplete abortion, inevitable abortion) must be excluded before performing this procedure.

14:
Pregnancy testing can be performed by measurement of either a serum or urine HCG and may be documented in the medical record by either the PCP, a gynecologist, or a surgeon.

15:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- BSO or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- BSO or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- BSO or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- BSO or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- BSO or Bilateral Salpingectomy - Outpatient

16:
A course of antibiotic therapy should be tried before determining if an oophorectomy is necessary. Nonresponders who have persistent pain, fever, or leukocytosis may need surgical intervention (Rosen et al., Obstet Gynecol Surv 2009, 64: 681-9). Factors that predict the need for intervention beyond antibiotic therapy include large abscess size, high white blood cell count, older age, and increased parity (Greenstein et al., The Journal of reproductive medicine 2013, 58: 101-6).

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy +/- BSO or Bilateral Salpingectomy for Pelvic inflammatory disease (PID) or Tubo-ovarian abscess (TOA)

ICD-10-CM (circle all that apply): C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C79.82, D06.0, D06.1, D06.7, D06.9, D25.0, D25.1, D25.2, D25.9, N70.01, N70.02, N70.03, N70.11, N70.12, N70.13, N70.91, N70.92, N70.93, N71.1, N71.9, N72, N73.1, N73.4, N73.8, N73.9, N80.0, N80.1, N80.2, N80.3, N80.4, N80.5, N80.6, N80.8, N80.9, N81.2, N81.3, N81.4, N85.00, N85.01, N85.02, N87.0, N87.1, N87.9, N92.1, N92.4, N92.5, N93.0, N93.1, N93.8, N93.9, N95.0, O01.0, O01.1, O01.9, O72.0, O72.1, O72.2, O72.3, R10.10, R10.11, R10.12, R10.13, R10.2, R10.30, R10.31, R10.32, R10.33, R10.811, R10.812, R10.813, R10.814, R10.815, R10.816, R10.817, R10.819, R10.821, R10.822, R10.823, R10.824, R10.825, R10.826, R10.827, R10.829, R10.83, R10.84, R10.9, R19.00, R19.01, R19.02, R19.03, R19.04, R19.05, R19.06, R19.07, R19.09, R93.5, Z14.8, Z15.01, Z15.02, Z15.04, Z15.09, Z15.89, Other _____

ICD-10-PCS (circle all that apply): 0UT20ZZ, 0UT24ZZ, 0UT28ZZ, 0UT2FZZ, 0UT70ZZ, 0UT74ZZ, 0UT78ZZ, 0UT7FZZ, 0UT90ZL, 0UT90ZZ, 0UT94ZL, 0UT94ZZ, 0UT98ZL, 0UT98ZZ, 0UT9FZL, 0UT9FZZ, 0UTC0ZZ, 0UTC4ZZ, 0UTC8ZZ, Other _____

CPT® (circle all that apply): 58150, 58152, 58180, 58541, 58542, 58543, 58544, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573, 58575, Other _____

InterQual®

2021, Oct. 2021 Release CP:Procedures

Subset: Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11]

Requested Service: Hysterectomy +/- Salpingo-Oophorectomy or Salpingectomy for Endometriosis

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Endometriosis by laparoscopy

1. Treatment within last year, Choose all that apply:
   - ☐ A) GnRH agonist ≥ 8 weeks [12]
   - ☐ B) Hormone therapy ≥ 8 weeks [13]
   - ☐ C) Danazol ≥ 8 weeks [14]
   - ☐ D) Other clinical information (add comment)

   > • If 1 or more options A, B or C selected and option D not selected, then go to question 2
   > • No other options lead to the requested service

2. Continued symptoms after treatment [15]
   - ☐ A) Yes
   - ☐ B) No

   > • If option Yes selected, then go to question 3
   > • No other options lead to the requested service

EXHIBIT
25

DHHRBMS001103

Endometriosis by laparoscopy (continued...)

3. Choose all that apply:
   - ☐ A) Most recent cervical cytology normal or managed per guidelines [16]
   - ☐ B) Pregnancy excluded by negative HCG or HCG planned prior to procedure or sterilization by history or patient not sexually active by history [17, 18, 19, 20]
   - ☐ C) Other clinical information (add comment)

> • If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here [21]
>
> • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

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3:
Whether to perform prophylactic oophorectomy at the time of hysterectomy done for benign disease in premenopausal women may be considered. There are no published randomized studies to support conservation or prophylactic removal of the ovaries, although observational studies suggest that surgical menopause may increase cardiovascular and overall mortality risk (Orozco et al., The Cochrane database of systematic reviews 2014, 7: CD005638). Generally, bilateral salpingo-oophorectomy (BSO) is recommended for women with BRCA1 or BRCA2 mutations or Lynch syndrome, for postmenopausal women, and for women who have invasive endometrial or ovarian carcinoma (National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: breast and ovarian (Version 3.2019). 2019; National Comprehensive Cancer Network, The NCCN clinical practice guidelines in oncology, genetic/familial high-risk assessment: colorectal (Version 3.2019). 2019). BSO may also be considered in women who have chronic pelvic pain, pelvic inflammatory disease, or endometriosis, although the risks of surgery should be balanced against the anticipated benefits. Ovarian retention should be considered for premenopausal women who do not have a genetic predisposition to ovarian cancer. Ovarian epithelial carcinoma may originate in cells from the fallopian tube. Therefore, salpingectomy without oophorectomy may be considered in low-risk women who undergo hysterectomy or other pelvic surgery for benign disease, which reduces the risk of ovarian cancer without the development of surgical menopause (American College of Obstetrics and Gynecologists, Obstet Gynecol 2019, 133: e279-e84; Society of Gynecologic Oncology, SGO Clinical Practice Statement: Salpingectomy for Ovarian Cancer Prevention 2013).

4:
Although robotic-assisted hysterectomy is being done, there are few prospective studies comparing robotic assisted to laparoscopic surgery for treating benign disease (ACOG, Obstetrics and Gynecology Committee Opinion No. 628. 2015, 125: 760-7. Reaffirmed 2017; Yu et al., Journal of surgical oncology 2013, 107: 653-8). A Cochrane review, however, demonstrated that robotic-assisted gynecologic surgery required more intraoperative time but reduced hospital stay when compared to laparoscopic surgery. There is no clear evidence to determine which surgery has the lowest complication rate (Liu et al., The Cochrane database of systematic reviews 2014, 12: CD011422). Robotic-assisted surgery can be performed as an outpatient surgery in some patients (Lawrie et al., Cochrane Database Syst Rev 2019, 4: Cd011422).

5:
Total laparoscopic hysterectomy (TLH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are then secured by the endoscopic route. The fundus is then divided and removed through the abdominal wall incisions.

6:
Vaginal hysterectomy offers many advantages to the abdominal or laparoscopic approach including no abdominal incision, less pain, and quicker recovery; if technically feasible, it is the preferred surgical route (American College of Obstetricians and Gynecologists (ACOG), Obstet Gynecol 2017, 129: e155-e9; Sesti et al., Archives of Gynecology and Obstetrics 2014, 290: 485-91). The vaginal technique, however, can be limited in its ability to treat ovarian pathology in large uteri. The preoperative use of GnRH agonists may help shrink large uteri so that a vaginal hysterectomy can be performed (Elzaher et al., European Journal of Obstetrics, Gynecology, and Reproductive Biology 2013, 169: 326-30). Vaginal hysterectomy may be difficult to perform in nulliparous women, obese women, and women with a history of cesarean delivery.

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Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

8:
Laparoscopically assisted vaginal hysterectomy (LAVH) is performed by mobilization of the uterus and its upper pedicles laparoscopically; the uterine vessels are not secured by the endoscopic route. A vaginal hysterectomy is then performed.

9:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting

10:
For cervical cancer stage I-IIA and endometrial cancer stage II, see the "Hysterectomy, Radical" criteria subset.

11:
Supracervical hysterectomy (subtotal hysterectomy) performed as an open or laparoscopic procedure has been thought to preserve sexual, bladder, and bowel function by minimizing disruption of the pelvic floor support and neurovascular supply when compared with total hysterectomy. However, there is inconsistent evidence to show there is an improvement or significant difference in surgical complications, incontinence rate, bladder function, or sexual function when subtotal hysterectomy is compared to total hysterectomy (Lethaby et al., Cochrane Database Syst Rev 2012, 4: CD004993). One 5-year follow-up study of a randomized controlled trial, however, did show higher rates of urinary incontinence and vaginal bleeding in women who had a supracervical hysterectomy compared with those who had a total hysterectomy (Andersen et al., BJOG: An International Journal of Obstetrics and Gynaecology 2015, 122: 851-7). Disadvantages of supracervical hysterectomy include cervical stump complications (e.g., bleeding, pain) and the small risk of developing cervical cancer in the cervical stump (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013). Supracervical hysterectomy may not be appropriate in women who have gynecological cancers, endometrial hyperplasia, or cervical dysplasia (ACOG, Obstet Gynecol 2007 Committee Opinion No. 388; 110(5): 1215-1217. Reaffirmed, 2013).

12:
The GnRH agonists include leuprolide, nafarelin, and goserelin. These compounds mimic the action of GnRH and, thereby, suppress the hormones produced by the ovary that stimulate endometrial growth.

13:
Medical therapy to treat symptoms of endometriosis may include combined contraceptive or progestin alone; their use is considered a first-line option (Brown and Farquhar, The Cochrane database of systematic reviews 2014, 3: CD009590). Depot medroxyprogesterone acetate, the progestin contraceptive implant, and the levonorgestrel intra-uterine system may also improve pain due to endometriosis (ACOG, Obstetrics and gynecology Practice Bulletin No. 110. 2010, 115: 206-218. Reaffirmed 2018).

14:
If symptoms do not respond to an oral contraceptive pill or GnRH agonist, then treatment with danazol or a progestin (e.g., depot medroxyprogesterone) is appropriate (Brown and Farquhar, Cochrane Database Syst Rev 2014: Cd009590).

15:
Symptoms of endometriosis include chronic recurrent pelvic pain, dysmenorrhea, infertility, and dyspareunia.

16:
Cervical cytology should be evaluated according to current screening protocols. Screening intervals and tests used (cervical cytology alone, high-risk human papillomavirus [hrHPV] testing alone, hrHPV and cytology together [co-testing]) will vary based on patient's age and risk factors. If the most recent cervical cytology is documented as normal, no further testing is needed. Any abnormalities detected during cervical cancer screening should be managed according to current guidelines. Management may include repeat testing, observation, surveillance, biopsy, ablation, or excisional treatment based on the identified level of risk for each patient (Redman et al., Eur J Obstet Gynecol Reprod Biol 2021, 256: 57-62; Perkins et al., J Low Genit Tract Dis 2020, 24: 102-31; US Preventative Services Task Force et al., JAMA 2018, 320: 674-86; Wentzensen et al., J Low Genit Tract Dis 2017, 21: 216-22).

17:
Pregnancy and related complications (e.g., ectopic pregnancy, incomplete abortion, inevitable abortion) must be excluded before performing this procedure.

18:
Pregnancy testing can be performed by measurement of either a serum or urine HCG and may be documented in the medical record by either the PCP, a gynecologist, or a surgeon.

19:
The documentation should include a history of sterilization (i.e., tubal ligation) without a subsequent pregnancy. These criteria do not include sterilization of a partner or alternate birth control methods (e.g., oral contraceptive pill use, intrauterine device insertion).

20:
Patients have varying definitions of sexual activity (e.g., number of partners, timing of most recent episode, frequency of sexual activity). Unless the provider can confirm on examination that the patient has never had sexual intercourse, whether a patient is sexually active or not is a matter of clinical judgment.

21:
I/O Setting:
Hysterectomy, Abdominal, Supracervical +/- Bilateral Salpingo-oophorectomy (BSO) - Inpatient
Hysterectomy, Abdominal, Total +/- Bilateral Salpingo-oophorectomy (BSO) - Inpatient
Hysterectomy, Laparoscopically Assisted Vaginal (LAVH) +/- Bilateral Salpingo-oophorectomy (BSO) - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting
Hysterectomy, Laparoscopic, Supracervical +/-Bilateral Salpingo-oophorectomy (BSO) - Outpatient
Hysterectomy, Laparoscopic, Total (TLH) +/- Bilateral Salpingo-oophorectomy (BSO) - Outpatient
Hysterectomy, Vaginal +/- Bilateral Salpingo-oophorectomy (BSO) - Due to variations in practice, this procedure can

be performed in the inpatient or outpatient setting

Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy

Hysterectomy +/- Salpingo-Oophorectomy or Salpingectomy for Endometriosis

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ICD-10-CM (circle all that apply): C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C79.82, D06.0, D06.1, D06.7, D06.9, D25.0, D25.1, D25.2, D25.9, N70.01, N70.02, N70.03, N70.11, N70.12, N70.13, N70.91, N70.92, N70.93, N71.1, N71.9, N72, N73.1, N73.4, N73.8, N73.9, N80.0, N80.1, N80.2, N80.3, N80.4, N80.5, N80.6, N80.8, N80.9, N81.2, N81.3, N81.4, N85.00, N85.01, N85.02, N87.0, N87.1, N87.9, N92.1, N92.4, N92.5, N93.0, N93.1, N93.8, N93.9, N95.0, O01.0, O01.1, O01.9, O72.0, O72.1, O72.2, O72.3, R10.10, R10.11, R10.12, R10.13, R10.2, R10.30, R10.31, R10.32, R10.33, R10.811, R10.812, R10.813, R10.814, R10.815, R10.816, R10.817, R10.819, R10.821, R10.822, R10.823, R10.824, R10.825, R10.826, R10.827, R10.829, R10.83, R10.84, R10.9, R19.00, R19.01, R19.02, R19.03, R19.04, R19.05, R19.06, R19.07, R19.09, R93.5, Z14.8, Z15.01, Z15.02, Z15.04, Z15.09, Z15.89, Other _____

ICD-10-PCS (circle all that apply): 0UT20ZZ, 0UT24ZZ, 0UT27ZZ, 0UT28ZZ, 0UT2FZZ, 0UT70ZZ, 0UT74ZZ, 0UT77ZZ, 0UT78ZZ, 0UT7FZZ, 0UT90ZL, 0UT90ZZ, 0UT94ZL, 0UT94ZZ, 0UT97ZL, 0UT97ZZ, 0UT98ZL, 0UT98ZZ, 0UT9FZL, 0UT9FZZ, 0UTC0ZZ, 0UTC4ZZ, 0UTC7ZZ, 0UTC8ZZ, Other _____

CPT® (circle all that apply): 58150, 58152, 58180, 58260, 58262, 58263, 58290, 58291, 58292, 58541, 58542, 58543, 58544, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573, 58575, Other _____

InterQual®

2021, Oct. 2021 Release CP:Procedures

Subset: Salpingo-Oophorectomy, Bilateral or Oophorectomy, Bilateral (1, 2, 3)

Requested Service: Salpingectomy-Oophorectomy, Bilateral

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Stage IB ovarian cancer

There are no questions for the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
Emerging data suggest that ovarian epithelial carcinoma may originate in cells from the fallopian tube, not just the ovaries. Therefore, prophylactic salpingectomy may reduce the risk of ovarian cancer, and can be considered in women who undergo hysterectomy or other pelvic surgery for benign disease. Salpingectomy without oophorectomy allows for ovarian cancer risk reduction without the development of surgical menopause (American College of Obstetrics and Gynecologists, Obstet Gynecol 2019, 133: e279-e84). For criteria for prophylactic salpingectomy, see the "Salpingectomy" criteria subset.

2:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

3:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

ICD-10-CM (circle all that apply): C56.1, C56.2, C56.3, C56.9, N80.1, N80.2, N80.8, N80.9, Z15.01, Z15.02, Z15.09, Z80.3, Z80.41, Other _____

ICD-10-PCS (circle all that apply): 0UT20ZZ, 0UT24ZZ, 0UT27ZZ, 0UT28ZZ, 0UT2FZZ, 0UT70ZZ, 0UT74ZZ, 0UT77ZZ, 0UT78ZZ, 0UT7FZZ, Other _____

CPT® (circle all that apply): 58661, 58720, 58950, Other _____

2012.2 Procedures Adult Criteria

Breast Reconstruction[1, 2, 3]

PATIENT:	Name	D.O.B.	ID#	GROUP#
CPT®/ICD:	Code	Facility	Service Date	
PROVIDER:	Name		ID#	Phone#
	Signature		Date	

ICD-9:

ICD-10:

CPT®:

INDICATIONS (choose one and see below)

- ☐ 100 Reconstruction post mastectomy
- ☐ 200 Reconstruction post partial mastectomy/lumpectomy
- ☐ 300 Reconstruction of contralateral breast post mastectomy
- ☐ Indication Not Listed (Provide clinical justification below)

☐ 100 Reconstruction post mastectomy **[One]**[4]
- ☐ 110 Immediate reconstruction at time of mastectomy
- ☐ 120 Delayed reconstruction with clear margins by pathology

☐ 200 Reconstruction post partial mastectomy/lumpectomy **[One]**[5]
- ☐ 210 Immediate reconstruction at time of partial mastectomy/lumpectomy
- ☐ 220 Delayed reconstruction **[Both]**
  - ☐ 221 With clear margins by pathology
  - ☐ 222 Adjuvant Rx completed[6]

☐ 300 Reconstruction of contralateral breast post mastectomy[7*RIN, 8]

EXHIBIT
50

DHHRBMS002754

Notes

(1)

Implant/Tissue Expander - Outpatient

Autologous Tissue Reconstruction - Inpatient

(2)

There are many procedures for breast reconstruction after mastectomy including reconstruction using tissue expanders and implants (either saline or silicone), autologous tissue reconstruction (e.g., pedicle or free flaps of the transverse rectus abdominal muscle, latissimus dorsi muscle), or an autologous flap and breast implant combination (Fernandez-Frias et al., J Am Coll Surg 2009; 208(1): 126-133; Hu and Alderman, Surg Clin North Am 2007; 87(2): 453-467, x). These criteria do not specify the type of procedure. Which procedure to perform is a matter of clinical judgement.

(3)

Chronic conditions that should be assessed prior to reconstructive surgery that are significant risk factors include obesity, nicotine use, diabetes, and chronic obstructive pulmonary disease (Hu and Alderman, Surg Clin North Am 2007; 87(2): 453-467, x).

(4)

There is not consensus or specific guidelines regarding the choice of immediate versus delayed breast reconstruction after a mastectomy (Fernandez-Frias et al., J Am Coll Surg 2009; 208(1): 126-133).

(5)

While breast reconstruction surgery post partial mastectomy or lumpectomy is uncommon, surgery such as a local perforator flap may be necessary in the smaller breasted woman to achieve symmetry.

(6)

Adjuvant therapy may consist of radiation or chemotherapy.

(7)-RIN:

For reduction mammoplasty, see the "Reduction Mammoplasty, Female" criteria subset.

(8)

Contralateral breast surgery may be necessary to achieve symmetry. These procedures may include reduction mammoplasty, augmentation, or mastopexy.

ICD-9:	85.50, 85.53, 85.54, 85.70, 85.71, 85.72, 85.73, 85.74, 85.75, 85.76, 85.79, 85.84, 85.85
ICD-10-PCS:	0H0T07Z, 0H0T0JZ, 0H0T0KZ, 0H0T37Z, 0H0T3JZ, 0H0T3KZ, 0H0TX7Z, 0H0TXJZ, 0H0TXKZ, 0H0U07Z, 0H0U0JZ, 0H0U0KZ, 0H0U37Z, 0H0U3JZ, 0H0U3KZ, 0H0UX7Z, 0H0UXJZ, 0H0UXKZ, 0H0V07Z, 0H0V0JZ, 0H0V0KZ, 0H0V37Z, 0H0V3JZ, 0H0V3KZ, 0H0VX7Z, 0H0VXJZ, 0H0VXKZ, 0HRT075, 0HRT076, 0HRT077, 0HRT078, 0HRT079, 0HRT07Z, 0HRT0JZ, 0HRT0KZ, 0HRU075, 0HRU076, 0HRU077, 0HRU078, 0HRU079, 0HRU07Z, 0HRU0JZ, 0HRU0KZ, 0HRV075, 0HRV076, 0HRV077, 0HRV078, 0HRV079, 0HX5XZZ, 0KXH0ZZ, 0KXH4ZZ, 0KXJ0ZZ, 0KXJ4ZZ, 0KXK0Z6, 0KXK4Z6, 0KXL0Z6, 0KXL4Z6
CPT®:	19324, 19325, 19340, 19342, 19357, 19361, 19364, 19366, 19367, 19368, 19369

2012.2 Procedures Adult Criteria

Mastectomy, Modified Radical (MRM)[1, 2]

PATIENT:	Name	D.O.B.	ID#	GROUP#
CPT®/ICD:	Code	Facility	Service Date	
PROVIDER:	Name		ID#	Phone#
	Signature		Date	

ICD-9:

ICD-10:

CPT®:

INDICATIONS (choose one and see below)

☐ 100 Invasive breast cancer
☐ 200 Palliative debulking for locally advanced breast cancer
☐ Indication Not Listed (Provide clinical justification below)

☐ 100 Invasive breast cancer **[Both]**
- ☐ 110 By Bx
- ☐ 120 No distant metastases[3]

☐ 200 Palliative debulking for locally advanced breast cancer[4]

EXHIBIT
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InterQual®

2012.2 Procedures Adult Criteria
Mastectomy, Modified Radical (MRM)

Notes

(1)-DEF:
A modified radical mastectomy (MRM) involves removal of the entire breast and axillary lymph nodes, sparing the pectoral muscle.

(2)
Studies show that partial mastectomy or lumpectomy with postoperative radiation offers similar survival and local control as MRM. MRM is done, rather than partial mastectomy, if there is fixation or invasion of the chest wall or skin. Other factors that may influence the choice of procedure include anaplastic cell type, multicentric disease, extensive intraductal involvement, inability to obtain adequate margins with lumpectomy, and size of lesion relative to breast size (Carlson et al., J Natl Compr Canc Netw 2009; 7(2): 122-192; American College of Radiology, J Am Coll Surg 2007; 205(2): 362-376). In the absence of restricting medical or pathological factors, the decision to perform MRM or lumpectomy is ultimately based on patient preference (McCready et al., Can J Surg 2005; 48(3): 185-194).

(3)
Bone scan, liver scan, and CT are used for the detection of metastases in patients with breast cancer and a high pretest probability of metastasis. When the clinical assessment, CXR, and blood tests (including alkaline phosphatase and LFTs) are normal, these scans have very low yield (Carlson et al., J Natl Compr Canc Netw 2009; 7(2): 122-192).

(4)
While systemic therapy can control metastatic cancer, it cannot cure it. MRM is performed if systemic therapy (chemotherapy or hormonal therapy) cannot control tumor growth and there is impending skin breakdown or chest wall invasion. If the tumor erodes into a blood vessel, the mastectomy may need to be performed urgently.

InterQual®

2012.2 Procedures Adult Criteria
Mastectomy, Modified Radical (MRM)

ICD-9: 85.43
ICD-10-PCS: 0HTT0ZZ, 0HTU0ZZ, 0HTV0ZZ
CPT®: 19307

2012.2 Procedures Adult Criteria

Mastectomy, Partial, +/- Axillary Dissection[1, 2*MDR, 3, 4]

PATIENT:	Name	D.O.B.	ID#	GROUP#
CPT®/ICD:	Code	Facility	Service Date	
PROVIDER:	Name		ID#	Phone#
	Signature		Date	

ICD-9:

ICD-10:

CPT®:

INDICATIONS (choose one and see below)

- ☐ 100 Invasive breast cancer
- ☐ 200 Palliative debulking for locally advanced breast cancer
- ☐ Indication Not Listed (Provide clinical justification below)

- ☐ 100 Invasive breast cancer **[All]**
  - ☐ 110 By Bx
  - ☐ 120 No fixation to/invasion of skin/chest wall **[≥ One]**[5]
    - ☐ 121 By PE
    - ☐ 122 By imaging[6]
  - ☐ 130 No distant metastases[7]

- ☐ 200 Palliative debulking for locally advanced breast cancer[8]

EXHIBIT
52

Notes

(1)
These criteria include the following procedures:
Lumpectomy
Mastectomy, Segmental
Quadrantectomy

(2)-MDR:
Axillary node dissection is not indicated for ductal carcinoma in situ (DCIS) or lobular carcinoma in situ (LCIS) (Carlson et al., J Natl Compr Canc Netw 2009; 7(2): 122-192). Because these findings by pathology demonstrate noninvasive disease, requests for axillary node dissection in these patients require secondary medical review.

(3)
Breast-conserving treatment is a term that encompasses lumpectomy, partial mastectomy, quadrantectomy, or segmental mastectomy procedures. Breast-conserving treatment is excision of the primary tumor and adjacent breast tissue typically followed by irradiation. The choice of breast-conserving treatment or modified radical mastectomy (MRM) is determined by the extent of disease and the ability of the patient to tolerate radiation therapy. For breast conserving surgery, the tumor size must be small enough to ensure complete tumor removal with an acceptable cosmetic outcome (Hammer et al., Cleve Clin J Med 2008; 75 Suppl 1: S10-16). Reported survival rates of ≥ 5 years following breast-conserving treatment have been shown in many studies to be similar to that of MRM (Carlson et al., J Natl Compr Canc Netw 2009; 7(2): 122-192; Jatoi and Proschan, Am J Clin Oncol 2005; 28(3): 289-294). Although appropriate for many patients, breast-conserving treatment remains underutilized as a treatment option, in part due to inappropriate patient selection, socioeconomic disparities, geographic practice patterns, and patient concerns over lifetime risk and fear of recurrence (Lee et al., Breast J 2009; 15(1): 34-40; McGuire et al., Ann Surg Oncol 2009; 16(10): 2682-2690; Smith et al., J Am Coll Surg 2009; 209(4): 425-433 e422).

(4)
There are few studies regarding long-term survival and recurrence rates of breast-conserving treatment for males with invasive breast cancer (Lanitis et al., J Med Case Reports 2008; 2: 126; Golshan et al., Breast 2007; 16(6): 653-656). Difficulty obtaining clear margins with the small volume of available breast tissue has made simple mastectomy the preferred treatment (Contractor et al., World J Surg Oncol 2008; 6: 58).

(5)
The chest wall is defined as structures deep to the pectoral muscles.

(6)
Imaging may include mammography or US.

(7)
Bone scan, liver scan, and CT are used for the detection of metastases in patients with breast cancer and a high pretest probability of metastasis. When the clinical assessment, CXR, and blood tests (including alkaline phosphatase and LFTs) are normal, these scans have very low yield (Carlson et al., J Natl Compr Canc Netw 2009; 7(2): 122-192).

(8)
The mastectomy (and removal of enlarged axillary nodes) is performed for local control of disease.

InterQual®

2012.2 Procedures Adult Criteria
Mastectomy, Partial, +/- Axillary Dissection

ICD-9: 40.23, 85.20, 85.21, 85.22, 85.23
ICD-10-PCS: 0H5T0ZZ, 0H5U0ZZ, 0H5V0ZZ, 0HBT0ZZ, 0HBU0ZZ, 0HBV0ZZ
CPT®: 19301, 19302

DHHRBMS002762

2012.2 Procedures Adult Criteria

Mastectomy, Prophylactic, Total/Simple[1*RIN, 2, 3]

PATIENT:	Name	D.O.B.	ID#	GROUP#
CPT®/ICD:	Code	Facility	Service Date	
PROVIDER:	Name		ID#	Phone#
	Signature		Date	

ICD-9:

ICD-10:

CPT®:

INDICATIONS (choose one and see below)

☐ 100 Woman w/o breast cancer by Hx
☐ 200 Woman with invasive breast cancer of contralateral breast
☐ Indication Not Listed (Provide clinical justification below)

☐ 100 Woman w/o breast cancer by Hx **[One]**
- ☐ 110 BRCA1/BRCA2 gene mutation by genetic testing[4, 5]
- ☐ 120 Atypical breast hyperplasia by Bx[6]
- ☐ 130 Diffuse microcalcifications
- ☐ 140 Breast cancer in first degree relative by Hx **[One]**[7, 8]
  - ☐ 141 ≥ 2 first degree relatives with unilateral breast cancer[9]
  - ☐ 142 ≥ 1 first degree relative with bilateral breast cancer[9]
  - ☐ 143 ≥ 1 first degree relative with premenopausal breast cancer

☐ 200 Woman with invasive breast cancer of contralateral breast[10, 11]

EXHIBIT
53

DHHRBMS002763

InterQual®

2012.2 Procedures Adult Criteria
Mastectomy, Prophylactic, Total/Simple

Notes

(1)-RIN:
These criteria cover requests for either unilateral or bilateral prophylactic mastectomy.

(2)-DEF:
A total or simple mastectomy involves the removal of nearly all breast tissue with the nipple-areolar complex.

(3)
Prophylactic mastectomy is one option that may reduce the risk of breast cancer in women who are at high risk for developing the disease. Women at high risk include those with BRCA1 or BRCA2 mutations, a positive family history, or breast cancer in the other breast. Although studies have shown risk reduction of ≥ 90% with this surgery, there is insufficient evidence that it improves overall survival (American College of Obstetricians and Gynecologists, Obstet Gynecol 2009; 113(4): 957-966; Giuliano et al., Ann Surg Oncol 2007; 14(9): 2425-2427; Lostumbo et al., Cochrane Database Syst Rev 2004; (4): CD002748).

(4)
Up to 10% of all breast and ovarian cancers are believed to be hereditary. Analysis of the BRCA1 and BRCA2 genes can identify an individual's predisposition to developing breast or ovarian cancer. BRCA1 and BRCA2 are tumor-suppressor genes responsible for regulating the growth of breast epithelial cells. Mutations of either of these genes can result in uninhibited growth of these cells. The estimated lifetime risk of developing breast cancer for those with a BRCA mutation is estimated to be 65% to 74% (American College of Obstetricians and Gynecologists, Obstet Gynecol 2009; 113(4): 957-966). Male mutation carriers have a 5% to 10% lifetime risk of developing breast cancer (Berliner and Fay, J Genet Couns 2007; 16(3): 241-260).

(5)
Women with a BRCA1 or BRCA2 gene mutation are also more likely to develop breast cancer at an earlier age. The risk of developing cancer varies depending on the penetrance of the gene mutation (e.g., higher life expectancy for low-penetrance mutations) (Jatoi and Anderson, Surg Clin North Am 2008; 88(4): 845-861, vii-viii). These mutations are commonly seen in families of Ashkenazi ancestry; an estimated 1 in 40 Ashkenazi Jews carry the mutation (American College of Obstetricians and Gynecologists, Obstet Gynecol 2009; 113(4): 957-966).

(6)
Women with atypical hyperplasia have a four- to five-fold increased risk of developing breast cancer (Hollingsworth et al., Am J Surg 2004; 187(3): 349-362). Atypical hyperplasia is more strongly associated with the development of premenopausal breast cancer than with postmenopausal disease (Vogel, Surg Clin North Am 2003; 83(4): 733-751).

(7)-DEF:
A first degree relative is defined as a blood-related sibling, parent, or child.

(8)
The listed family history patterns have been associated with an increased incidence of BRCA1 or BRCA2 gene mutations (U.S. Preventive Services Task Force, Am Fam Physic 2006; 73(5): 869-874).

(9)
A patient has a four- to six-fold increased risk of developing breast cancer if her 2 sisters had breast disease or her mother and a sister had unilateral breast cancer. There is a two-fold increase if a mother or sister had the disease. The patient is at even greater risk when the disease is bilateral (Willey and Cocilovo, Obstet Gynecol 2007; 110(6): 1404-1416; Nelson et al., Ann Intern Med 2005; 143(5): 362-379).

(10)
There is insufficient evidence to show improved disease-free survival rates in women who undergo prophylactic mastectomy performed on the breast contralateral to the diagnosed cancer. However, since the remaining breast is at increased risk for the development of cancer, patients report significant reduction in their anxiety levels when undergoing contralateral prophylactic mastectomy (Lostumbo et al., Cochrane Database Syst Rev 2004; (4): CD002748).

(11)
Despite advances in imaging and chemoprevention therapy, psychological factors may influence a woman to choose surgery, among them anxiety over having cancer, a need to reduce perceived risk of further cancer, and concern over being able to raise her children (Tan et al., Hered Cancer Clin Pract 2009; 7(1): 6; Yi et al., Cancer 2009; 115(5): 962-971; Tuttle et al., J Clin Oncol 2007; 25(33): 5203-5209).

DHHRBMS002764

InterQual®

2012.2 Procedures Adult Criteria
Mastectomy, Prophylactic, Total/Simple

ICD-9: 85.41, 85.42
ICD-10-PCS: 0HTT0ZZ, 0HTU0ZZ, 0HTV0ZZ
CPT®: 19303

InterQual®

2021, July 2021 Release CP:Procedures

Subset: Reduction Mammoplasty, Female (Adolescent) (1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14)

Requested Service: Reduction Mammoplasty, Female (Adolescent)

Age: Age ≥ 13 and < 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Choose one of the following options and continue to the appropriate section

- ☐ 10. Breast reduction of contralateral breast post-mastectomy
- ☐ 20. Macromastia or gigantomastia

☐ 10. Breast reduction of contralateral breast post-mastectomy

1. Choose one: (15)
   - ☐ A) Imaging within 1 year and negative for tumor or malignant changes
   - ☐ B) Imaging within 1 year and positive for tumor or malignant changes
   - ☐ C) Imaging not performed with 1 year of reduction mammoplasty
   - ☐ D) Other clinical information (add comment)

> • If option A selected, then the rule is satisfied; you may stop here **(Outpatient)**
> • No other options lead to the requested service

☐ 20. Macromastia or gigantomastia

1. Choose one:
   - ☐ A) Symptomatic macromastia or gigantomastia
   - ☐ B) Asymptomatic macromastia or gigantomastia (16)
   - ☐ C) Other clinical information

> • If option A selected, then go to question 2
> • No other options lead to the requested service

Reduction Mammoplasty, Female (Adolescent)

Macromastia or gigantomastia (continued...)

2. No change in cup-size for at least 6 months [17]
   - ☐ A) Yes
   - ☐ B) No

   • If option Yes selected, then go to question 3
   • No other options lead to the requested service

3. Choose all that apply: [18]
   - ☐ A) Chronic back or neck or shoulder pain and other etiologies excluded
   - ☐ B) Breast pain from excessive breast tissue and other etiologies excluded
   - ☐ C) Paresthesias of hands or arms and other etiologies excluded
   - ☐ D) Permanent shoulder grooving from bra straps
   - ☐ E) Persistent intertrigo at the inframammary folds [19]
   - ☐ F) Other clinical information (add comment)

   • If 2 or more options A, B, C, D or E selected and option F not selected, then go to question 4
   • No other options lead to the requested service

4. Choose one: [20]
   - ☐ A) Palpable mass or lesion on physical examination
   - ☐ B) Significant breast asymmetry
   - ☐ C) No palpable mass or lesion or breast asymmetry
   - ☐ D) Other clinical information (add comment)

   • If option C selected, then the rule is satisfied; you may stop here **(Outpatient)**
   • If option A or B selected, then go to question 5
   • No other options lead to the requested service

5. Choose one: [20, 21]
   - ☐ A) Biopsy or imaging negative for tumor or malignant changes
   - ☐ B) Biopsy positive for tumor or malignant changes
   - ☐ C) Imaging positive for tumor or malignant changes
   - ☐ D) Biopsy or imaging not performed
   - ☐ E) Other clinical information (add comment)

   • If option A selected, then the rule is satisfied; you may stop here **(Outpatient)**
   • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Reduction Mammoplasty, Female (Adolescent)

Notes:

1:
Unlike adult females who have reached skeletal maturity with known completed breast growth, the Schnur Scale, which quantifies a specific amount of breast tissue to be removed based on the patient's body surface area (BSA), does not appear to be used routinely for adolescents who plan for reduction mammoplasty. Retrospective studies have outlined estimates of breast tissue to be removed in this population. Rather than BSA, body mass index (BMI) seems to correlate with the amount of breast tissue taken out in adolescents. Although estimates were gathered postoperatively and were not used to determine medical appropriateness prior to surgery, these studies have some overlap suggesting the higher the BMI, the more breast tissue is removed. Generally, individuals with a healthy weight were estimated to have at least 650 grams removed bilaterally, overweight individuals at least 800 grams, and obese individuals were estimated to have at least 1,000 grams removed. More research is needed to clearly outline how many grams is appropriate to remove in each breast, as the current studies estimate total grams removed bilaterally and there are no guidelines on best practices in the adolescent population (Pike et al., J Adolesc Health 2015, 57: 277-81; Xue et al., J Pediatr Adolesc Gynecol 2013, 26: 228-33; Webb et al., Ann Plast Surg 2012, 68: 257-60).

2:
As with adult females, there is a strong association between macromastia and obesity in adolescents. Because the incidence of obesity is increasing at a younger age, it is often difficult for practitioners to distinguish between idiopathic macromastia or gigantomastia versus obesity-related macromastia or gigantomastia. Encouraging weight loss in adolescents may have some benefits such as decreased body mass index (BMI). However, required weight loss prior to reduction mammoplasty in adolescents remains controversial. Not only are many adolescents unable to participate in exercise because their large breast size poses a barrier, but they are often too embarrassed. Also, there is no evidence to support the theory that weight loss will reduce breast size to such a degree that will relieve symptoms of macromastia (Pike et al., J Adolesc Health 2015, 57: 277-81; Wolfswinkel et al., Semin Plast Surg 2013, 27: 49-55).
A small retrospective study concluded that reduction mammoplasty did not show significant decrease in BMI in this population at a two-year follow-up assessment. Instead, there was a small increase in BMI seen among overweight and obese patients. Practice varies in terms of weight loss requirements prior to surgery. As weight loss may be encouraged to prevent postoperative complications and promote healthy eating habits, literature suggests additional diet and nutritional counseling and exercise programs be initiated prior to surgery and encouraged post-surgery (Pike et al., J Adolesc Health 2015, 57: 277-81; Wolfswinkel et al., Semin Plast Surg 2013, 27: 49-55). Surgical intervention should be performed to treat physiological symptoms of macromastia (e.g., back, shoulder or neck pain, bra strap grooving), rather than be used as weight loss treatment or serve as motivation for adolescents to participate in exercise more regularly (Pike et al., J Adolesc Health 2015, 57: 277-81).

3:
A large retrospective study analyzed national estimates of inpatient hospital stays for individual's ages 12 years to 20 years using the Agency for Healthcare Research and Quality Kids Inpatient Database from 2000 to 2009 who received reduction mammoplasty. This review states that surgery to treat macromastia is safe with few early postoperative complications accompanied with short hospital stays. Only 42 patients (3.19%) had complications (e. g., infections, hemorrhage, hematoma). Duration of stay was 1 day in 85% and less than 1 day was 3% (Soleimani et al., Surgery 2015, 158: 793-801).

4:
Literature reviews suggest that age should not determine the medical appropriateness of reduction mammoplasty in females with macromastia or gigantomastia. Instead, severity of symptoms should govern suitability for surgery. It has been proven that young females in their adolescence who suffer physically from macromastia or gigantomastia benefit from surgical intervention, have high satisfaction and symptom relief, would recommend surgery to others, and have significant improvement in emotional status (The American College of Obstetricians and Gynecologists (ACOG), ACOG Revises Breast Cancer Screening Guidance. 2017; Wolfswinkel et al., Semin Plast Surg 2013, 27: 49-55).

5:
This is a procedure that can be performed for either medically necessary or cosmetic purposes. The criteria as written are intended solely for use in determining the medical appropriateness of this procedure and do not cover this procedure when performed for cosmetic reasons.

Reduction Mammoplasty, Female (Adolescent)

6:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

7:
Retrospective studies demonstrate an overall low complication rate after breast reduction mammoplasty; however, a higher body mass index and smoking are associated with an increased risk for wound complications, reoperation, and a slower recovery (Imahiyerobo et al., Annals of Plastic Surgery 2015, 75: 370-5; Fischer et al., Aesthetic Surgery Journal/The American Society for Aesthetic Plastic surgery 2014, 34: 66-73; Gust et al., Aesthetic Surgery Journal/The American Society for Aesthetic Plastic surgery 2013, 33: 1140-7). These risks, along with weight loss and smoking cessation for appropriate patients, should be discussed preoperatively.

8:
Breast development is variable and may continue beyond the age of 18. Since there is a possibility of regrowth of tissue after mammoplasty, complete breast development is ideal prior to considering mammoplasty in adolescents; however, females younger than 18 years of age with no change in cup size for at least six months and who experience the same physical symptoms as adults are candidates for mammoplasty.

9:
I/O Setting: Outpatient

10:
These criteria address medically necessary surgical resection of macromastia or gigantomastia. If breast enlargement is due primarily to excessive fatty tissue, liposuction can be used. Liposuction has not been established as a medically necessary procedure for breast reduction, and is considered cosmetic, even when it is used in conjunction with mammoplasty to remove fatty tissue and glandular breast tissue. Liposuction is not covered in these criteria.

11:
POL: It is a matter of local medical policy whether to require submission of photographs prior to approval of the procedure.

12:
These criteria include the following procedure:
Breast Reduction, Female

13:
Reduction mammoplasty is associated with significant improvement in preoperative symptoms and quality of life, and has been shown to result in increased participation in exercise programs and other physical and social activities (Singh and Losken, Plast Reconstr Surg 2012, 129: 562-70). Studies, including the Breast Reduction Assessment of Outcome and Value study (BRAVO), reported that reduction mammoplasty reduced or eliminated symptoms of macromastia regardless of body weight, bra cup size, or weight of tissue resected (Cunningham et al., Plast Reconstr Surg 2005; 115(6): 1597-1604; Chadbourne et al., Mayo Clin Proc 2001; 76(5): 503-510). One systematic review of breast reduction, augmentation, and prophylactic subcutaneous mastectomy concluded that an increase in breast size is associated with an increased risk of breast cancer (Jansen et al., Journal of Plastic, Reconstructive & Aesthetic Surgery: JPRAS 2014, 67: 1615-23). A large retrospective study suggests that reduction mammoplasty is associated with decreasing risk of breast cancer in women (Carlson, Clin Plast Surg 2016, 43: 341-7).

14:

Reduction Mammoplasty, Female (Adolescent)

InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

15:
Women with a history of breast cancer are at an increased risk for recurrence. InterQual® external peer reviewers agree that imaging should be performed within one year of reduction mammoplasty of the contralateral breast following mastectomy as imaging both breasts would have been done at the time of the mastectomy. If more than one year has lapsed, repeat imaging should be done to rule out tumor or malignant changes.

16:
Breast asymmetry, hypomastia, macromastia and gynecomastia can have significant psychosocial impact, not only in adolescent males and females, but also in adults. Retrospective and prospective studies using the Rosenberg Self-Esteem Scale state that these individuals often suffer from low self-esteem and seek surgery to relieve emotional instability (Nuzzi et al., Plast Reconstr Surg 2014, 134: 1116-23; Nuzzi et al., Plast Reconstr Surg 2013, 131: 890-6; Neto et al., Aesthetic Plast Surg 2012, 36: 223-5).

17:
Juvenile breast hypertrophy usually presents with excessive and rapid breast growth over a 6 month period (Wolfswinkel et al., Semin Plast Surg 2013, 27: 49-55). Ideally, surgical intervention to help reduce the size of breast tissue should not commence until the breast size has stabilized. The American College of Obstetricians and Gynecologists has not obtained consensus among practitioners regarding appropriate timing of reduction mammoplasty in adolescent females. InterQual® consultants agree that there be no change in cup-size for at least 6 months, or until the patient has reached skeletal maturity. Others rely heavily on the degree of breast ptosis or the severity of symptoms as the deciding factor regardless of breast growth completion (The American College of Obstetricians and Gynecologists (ACOG), Committee Opinion: Committee on Adolescent Health Care. 2017; Wolfswinkel et al., Semin Plast Surg 2013, 27: 49-55).

18:
The American Society of Plastic Surgeons defines symptomatic breast hypertrophy as a syndrome of persistent neck and shoulder pain, grooving from bra straps, chronic intertrigo rash of the inframammary fold, frequent episodes of headache, backache, and upper extremity peripheral neuropathies caused by the increase in volume and weight of breast tissue beyond normal proportions (American Society of Plastic Surgeons, Reduction Mammaplasty Evidence-Based Practice Guidelines 2011).

19:
Def: Intertrigo is a superficial dermatitis occurring on apposed skin surfaces which predisposes to erythema, maceration, itching, and secondary infection.

20:
Malignancy is extremely rare in women with macromastia or gigantomastia. Cause for concern would include significant breast asymmetry, mass, or lesions. Therefore, it may be appropriate to perform a biopsy or imaging study (e.g., ultrasound, mammogram, MRI) to rule out malignancy prior to breast reduction. Benign breast fibroadenomas should also be ruled out as they can be similar in appearance and symptomology to macromastia or gigantomastia (Wolfswinkel et al., Semin Plast Surg 2013, 27: 49-55).

21:
Imaging and biopsy can differentiate benign from malignant masses and can be used when screening is required based on a patient's age, or to rule out malignancy in patients who are symptomatic or have other high-risk factors.

Reduction Mammoplasty, Female (Adolescent)

ICD-10-CM (circle all that apply): N60.11, N60.12, N60.19, N62, N65.0, N65.1, Z85.3, Other _____

ICD-10-PCS (circle all that apply): 0H0T0JZ, 0H0T37Z, 0H0U0JZ, 0H0U3JZ, 0H0V0JZ, 0H0V3JZ, 0HBT0ZZ, 0HBT3ZZ, 0HBU0ZZ, 0HBU3ZZ, 0HBV0ZZ, 0HBV3ZZ, 0HRT0JZ, 0HRT3JZ, 0HRU0JZ, 0HRU3JZ, 0HRV0JZ, 0HRV3JZ, Other _____

CPT® (circle all that apply): 19318, Other _____

InterQual®

2021, July 2021 Release CP:Procedures

Subset: Reduction Mammoplasty, Male (Adolescent) (1, 2, 3, 4, 5, 6, 7, 8, 9)

Requested Service: Reduction Mammoplasty, Male (Adolescent)

Age: Age ≥ 13 and < 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Gynecomastia

1. Choose one:
   - ☐ A) Symptomatic gynecomastia
   - ☐ B) Asymptomatic gynecomastia (10)
   - ☐ C) Other clinical information

   > • If option A selected, then go to question 2
   > • No other options lead to the requested service

2. Choose all that apply:
   - ☐ A) Breast pain or tenderness (11)
   - ☐ B) Grade I or grade II or grade III or grade IV gynecomastia by physical examination (12, 13, 14)
   - ☐ C) Contributory conditions excluded or treated ≥ 6 months (15, 16)
   - ☐ D) Gynecomastia persists beyond 2 years of onset (17)
   - ☐ E) Other clinical information (add comment)

   > • If the number of options selected is 4 and option E not selected, then go to question 3
   > • No other options lead to the requested service

Reduction Mammoplasty, Male (Adolescent)

Gynecomastia (continued...)

3. Choose one: (18)
   - ☐ A) Medications deemed noncontributory
   - ☐ B) Contributory medications discontinued
   - ☐ C) Requires medication that contributes to gynecomastia for which there is no acceptable alternative medication
   - ☐ D) Other clinical information (add comment)

> • If option A, B or C selected, then the rule is satisfied; you may stop here **(Outpatient)**
> • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Reduction Mammoplasty, Male (Adolescent)

Notes:

1:
Gynecomastia is commonly seen in newborns, adolescents and men older than age 60, yet spontaneous resolution frequently occurs in newborns and adolescents and does not require intervention. Males whose gynecomastia does not resolve on its own and who are symptomatic may be candidates for reduction mammoplasty to remove glandular breast tissue (Dickson, Am Fam Physician 2012, 85: 716-22).

2:
POL: It is a matter of local medical policy whether to require submission of photographs prior to approval of the procedure.

3:
These criteria address surgical resection (e.g., reduction mammoplasty, subcutaneous mastectomy) of gynecomastia, including mixed gynecomastia. If breast enlargement in male patients is due primarily to excess fatty tissue and not glandular hypertrophy, liposuction can be used for reducing breast size. Since liposuction only removes fatty tissue and not breast tissue, liposuction is not covered by these criteria.

4:
These criteria include the following procedures:
Breast Reduction, Male
Mastectomy for Gynecomastia
Mastectomy, Subcutaneous, Male

5:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

6:
Nearly 50% to 65% of adolescent males will experience some degree of gynecomastia at Tanner stage 3 or 4. When spontaneous resolution does not occur, some males will pursue surgery due to physical symptoms, or because of significant emotional distress (Rew et al., J Adolesc 2015, 43: 206-12; Dickson, Am Fam Physician 2012, 85: 716-22). A large systematic review states that adolescent males with gynecomastia are often overweight or obese, yet do not experience significantly higher rates of complications after surgery than those who are normal weight. Weight loss prior to surgery may be advised in some cases to achieve normal weight for overall health reasons, but is not always necessary prior to reduction mammoplasty to prevent complications. Delaying surgery in symptomatic patients until weight loss is achieved is not advised as it may perpetuate emotional distress (Rew et al., J Adolesc 2015, 43: 206-12).

7:
This is a procedure that can be performed for either medically necessary or cosmetic purposes. The criteria as written are intended solely for use in determining the medical appropriateness of this procedure and do not cover this procedure when performed for cosmetic reasons.

8:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias

Reduction Mammoplasty, Male (Adolescent)

following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

9:
I/O Setting: Outpatient

10:
Breast asymmetry, hypomastia, macromastia and gynecomastia can have significant psychosocial impact, not only in adolescent males and females, but also in adults. Retrospective and prospective studies using the Rosenberg Self-Esteem Scale state that these individuals often suffer from low self-esteem and seek surgery to relieve emotional instability (Nuzzi et al., Plast Reconstr Surg 2014, 134: 1116-23; Nuzzi et al., Plast Reconstr Surg 2013, 131: 890-6; Neto et al., Aesthetic Plast Surg 2012, 36: 223-5).

11:
Gynecomastia is commonly associated with breast pain, which can range in intensity from mild tenderness or sensitivity to constant pain and pressure.

12:
True gynecomastia can present as a rubbery or firm, subareolar mass that can be unattached or adherent to the skin.

13:
The American Society of Plastic Surgeons has adopted the following grading system for gynecomastia (American Society of Plastic Surgeons, Practice Parameters: Gynecomastia. 2004). :
• Grade I: Small breast enlargement with localized button of tissue that is concentric around the areola
• Grade II: Moderate breast enlargement exceeding areola boundaries with edges that are indistinct from the chest
• Grade III: Moderate breast enlargement exceeding areola boundaries with edges that are distinct from the chest with skin redundancy present
• Grade IV: Marked breast enlargement with skin redundancy and feminization of the breast

14:
InterQual® consultants agree that adolescent males with grade I gynecomastia that has persisted for at least two years, who have discontinued all possible contributory medications, and who have breast pain or tenderness are candidates for medically necessary reduction mammoplasty.

15:
Medical conditions associated with gynecomastia include hypogonadism, hyperthyroidism, renal disease, malnutrition, cirrhosis or liver disease, testicular or prostate tumors, Klinefelter syndrome, and XXY males. Attempts should be made to address these underlying causes of gynecomastia prior to considering surgical resection.

16:
Medical treatment for gynecomastia involves blocking estrogen effects in the breast tissue using antiestrogens (e.g., tamoxifen), decreasing estrogen production using aromatase inhibitors (e.g., testactolone), or giving androgens (Morcos and Kizy, J Fam Pract 2012, 61: 719-25). While tamoxifen is not approved by the U.S. Food and Drug Administration for the treatment of gynecomastia, it has been well studied and does reduce breast pain and swelling. Gynecomastia that has been present for longer than 1 year and is fibrotic does not generally regress spontaneously or resolve with medication (Morcos and Kizy, J Fam Pract 2012, 61: 719-25).

17:
Spontaneous resolution of gynecomastia in adolescent males tends to occur within six months to two years of onset. If gynecomastia persists after two years, surgery can be considered (Dickson, Am Fam Physician 2012, 85: 716-22).

18:
An integral component in the evaluation of gynecomastia is recognizing and discontinuing or changing any drugs

Reduction Mammoplasty, Male (Adolescent)

that can cause the disorder, as the problem may recur after surgical correction if the drugs are continued. Medications that can cause breast enlargement include certain hormones, chemotherapeutic agents, psychoactive drugs, antibiotics, and antiulcer drugs, as well as drugs of abuse (e.g., marijuana, heroin, amphetamines, anabolic steroids) (Morcos and Kizy, J Fam Pract 2012, 61: 719-25).

Reduction Mammoplasty, Male (Adolescent)

ICD-10-CM (circle all that apply): N62, Other _____

ICD-10-PCS (circle all that apply): 0H0T0JZ, 0H0T3JZ, 0H0U0JZ, 0H0U3JZ, 0H0V0JZ, 0H0V3JZ, 0HBT0ZZ, 0HBT3ZZ, 0HBU0ZZ, 0HBU3ZZ, 0HBV0ZZ, 0HBV3ZZ, 0HRT0JZ, 0HRT3JZ, 0HRU0JZ, 0HRU3JZ, 0HRV0JZ, 0HRV3JZ, Other _____

CPT® (circle all that apply): 19300, 19318, Other _____

InterQual®

2012.2 Procedures Adult Criteria

Reduction Mammoplasty, Female[1, 2*RIN, 3]

PATIENT:	Name	D.O.B.	ID#	GROUP#
CPT®/ICD:	Code	Facility	Service Date	
PROVIDER:	Name		ID#	Phone#
	Signature		Date	

ICD-9:

ICD-10:

CPT®:

INDICATIONS (choose one and see below)

☐ 100 Macromastia (gigantomastia), bilateral
☐ 200 Breast reduction of contralateral breast post mastectomy
☐ Indication Not Listed (Provide clinical justification below)

☐ 100 Macromastia (gigantomastia), bilateral **[Both]**[4]
- ☐ 110 Symptoms **[≥ Two]**
  - ☐ 111 Back/neck/shoulder pain
  - ☐ 112 Breast pain
  - ☐ 113 Paresthesias of hands/arms
  - ☐ 114 Permanent shoulder grooving from bra straps
  - ☐ 115 Intertrigo[5]
- ☐ 120 Excess breast tissue per breast to be removed (estimated amount) **[≥ One]**[6, 7]
  - ☐ 121 199 g to 238 g and BSA 1.35 to 1.45
  - ☐ 122 239 g to 284 g and BSA 1.46 to 1.55
  - ☐ 123 285 g to 349 g and BSA 1.56 to 1.69
  - ☐ 124 ≥ 350 g

☐ 200 Breast reduction of contralateral breast post mastectomy[8]

EXHIBIT
56

DHHRBMS002778

Notes

(1)
These criteria include the following procedure:
Breast Reduction, Female
Mastectomy, Subcutaneous, Female

(2)-RIN:
Liposuction can be used for moderate reduction of primarily fatty breast tissue. Liposuction is not covered in these criteria.

(3)-POL:
It is a matter of local medical policy whether to require submission of photographs prior to approval of the procedure.

(4)
Reduction mammoplasty is associated with significant improvement in preoperative symptoms and quality of life, and has been shown to result in increased participation in exercise programs and other physical and social activities (Spector and Karp, Plast Reconstr Surg 2007; 120(4): 845-850).
Given the wide range of body habitus, it is difficult to define the size of breast enlargement that is pathologic. Macromastia has been defined as a chronic pain complex involving at least 3 anatomic sites of the upper body in women with bilateral breast hypertrophy (Blomqvist et al., Plast Reconstr Surg 2000; 106(5): 991-997). Bra size (e.g., greater than a D cup) and estimated amount of breast tissue to be removed (from 0.8 to 2.0 kg) have also been used to identify macromastia (Dancey et al., J Plast Reconstr Aesthet Surg 2008; 61(5): 493-502; Kerrigan et al., Plast Reconstr Surg 2001; 108(6): 1591-1599).
Weight loss is advisable from an overall health standpoint in the overweight patient, but there is no data to support the theory that weight loss will reduce breast size to such a degree as to relieve the symptoms of macromastia. Studies, including the Breast Reduction Assessment of Outcome and Value study (BRAVO), reported that reduction mammoplasty reduces or eliminates symptoms of macromastia regardless of body weight, bra cup size, or weight of tissue resected (Cunningham et al., Plast Reconstr Surg 2005; 115(6): 1597-1604; Chadbourne et al., Mayo Clin Proc 2001; 76(5): 503-510). Prospective studies on surgical and nonsurgical interventions in the treatment of macromastia demonstrated that while reduction mammoplasty improved pain and overall health status, conservative measures (e.g., weight loss) did not provide effective, permanent relief of symptoms (O'Blenes et al., Plast Reconstr Surg 2006; 117(2): 351-358; Miller et al., Plast Reconstr Surg 2005; 115(4): 1025-1031).

(5)-DEF:
Intertrigo is a superficial dermatitis occurring on apposed skin surfaces which predisposes to erythema, maceration, itching, and secondary infection.

(6)
The Schnur scale is one method to determine medical necessity and requires a specific amount of breast tissue be removed based on the patient's body surface area (BSA) (Dancey et al., J Plast Reconstr Aesthet Surg 2008; 61(5): 493-502; Schnur, Ann Plast Surg 1999; 42(1): 107-108).

(7)-POL:
Studies have correlated the weight of breast tissue removed with the likelihood of the procedure being done for medical or cosmetic purposes; however, this can only be used as a retrospective measure (Glatt et al., Plast Reconstr Surg 1999; 103(1): 76-82; Schnur, Ann Plast Surg 1999; 42(1): 107-108). Whether to use the Schnur scale or another scale to determine the medical appropriateness of this procedure is a matter of local medical policy.

(8)
After reconstruction or use of a prosthesis, breast reduction of the contralateral breast may be needed to achieve symmetry (Hu and Alderman, Surg Clin North Am 2007; 87(2): 453-467, x; Antoniuk, Obstet Gynecol Clin North Am 2002; 29(1): 209-223, ix.).

ICD-9: 85.31, 85.32, 85.33, 85.34, 85.36
ICD-10-PCS: 0HBT0ZZ, 0HBT3ZZ, 0HBU0ZZ, 0HBU3ZZ, 0HBV0ZZ, 0HBV3ZZ
CPT®: 19300, 19304, 19318

InterQual®

2012.2 Procedures Adult Criteria

Reduction Mammoplasty, Male[1, 2*RIN, 3]

PATIENT:	Name	D.O.B.	ID#	GROUP#
CPT®/ICD:	Code	Facility	Service Date	
PROVIDER:	Name		ID#	Phone#
	Signature		Date	

ICD-9:

ICD-10:

CPT®:

INDICATIONS (choose one and see below)

☐ 100 Gynecomastia, bilateral/unilateral
☐ Indication Not Listed (Provide clinical justification below)

☐ 100 Gynecomastia, bilateral/unilateral **[All]**[4, 5]
- ☐ 110 Breast pain/tenderness[6]
- ☐ 120 Grade II/III/IV gynecomastia by PE[7, 8, 9]
- ☐ 130 Mammogram/US negative for cyst/tumor[10]
- ☐ 140 Contributory conditions excluded/treated ≥ 6 mos[11, 12]
- ☐ 150 Medication review **[One]**[13]
  - ☐ 151 Medications deemed noncontributory
  - ☐ 152 Contributory medications discontinued
  - ☐ 153 Requires medication that contributes to gynecomastia for which there is no acceptable alternative medication

EXHIBIT 57

Notes

(1)
These criteria include the following procedures:
Breast Reduction, Male
Mastectomy for Gynecomastia
Mastectomy, Subcutaneous, Male

(2)-RIN:
These criteria address surgical resection (e.g., reduction mammoplasty, subcutaneous mastectomy) of gynecomastia. If breast enlargement in male patients is due primarily to excess fatty tissue and not glandular hypertrophy, liposuction can be used for breast reduction. Since liposuction only removes fatty tissue and not breast tissue, liposuction is not covered by these criteria.

(3)
In male patients, reduction mammoplasty is done for symptomatic gynecomastia and is performed as an open procedure or a combination of surgical excision and liposuction. The specific surgical technique will vary depending on the amount of glandular breast tissue and fat removed and the amount of skin resected. Surgical excision of breast tissue is used for true gynecomastia, as glandular tissue cannot be suctioned (Devalia and Layer, Surgeon 2009; 7(2): 114-119; Johnson and Murad, Mayo Clin Proc 2009; 84(11): 1010-1015). Reduction mammoplasty is indicated for gynecomastia not related to malignancy or caused by other treatable causes (Narula and Carlson, Endocrinol Metab Clin North Am 2007; 36(2): 497-519; American Society of Plastic Surgeons, Practice Parameters: Gynecomastia. 2004 [cited 2010]).

(4)-DEF:
True gynecomastia is a benign proliferation of the glandular component of male breast tissue and is caused by an excess of circulating estrogen, a deficiency of androgens, or an altered androgen-to-estrogen ratio. Pseudogynecomastia is breast enlargement due to fat or adipose accumulation. Mixed gynecomastia is breast enlargement secondary to both glandular and fat tissue.

(5)
Gynecomastia can occur in males of any age but is more commonly seen in puberty or in males over the age of 60 (Braunstein, N Engl J Med 2007; 357(12): 1229-1237; Hanavadi et al., Breast 2006; 15(2): 276-280). In more than half of all cases, gynecomastia occurs bilaterally. Carcinoma should be considered in cases of unilateral enlargement, induration, fixation, skin dimpling, bloody nipple discharge, or a hard, asymmetric mass (Johnson and Murad, Mayo Clin Proc 2009; 84(11): 1010-1015; Braunstein, N Engl J Med 2007; 357(12): 1229-1237; Narula and Carlson, Endocrinol Metab Clin North Am 2007; 36(2): 497-519).

(6)
Gynecomastia is commonly associated with breast pain, which can range in intensity from mild tenderness or sensitivity to constant pain and pressure (Narula and Carlson, Endocrinol Metab Clin North Am 2007; 36(2): 497-519; Di Lorenzo et al., Lancet Oncol 2005; 6(12): 972-979). Surgical resection would only be done in symptomatic patients.

(7)
Gynecomastia can be differentiated from pseudogynecomastia by comparing the subareolar, glandular breast tissue with the adjacent adipose tissue (Johnson and Murad, Mayo Clin Proc 2009; 84(11): 1010-1015; Narula and Carlson, Endocrinol Metab Clin North Am 2007; 36(2): 497-519). True gynecomastia usually presents as a rubbery, discrete subareolar mass that is freely mobile and unattached to the skin (Braunstein, N Engl J Med 2007; 357(12): 1229-1237).

(8)
Symptomatic gynecomastia that does not respond to medical treatment may require surgical intervention. A grading system aids in determining the appropriate surgical intervention for treating gynecomastia.
The American Society of Plastic Surgeons has adapted the various classification systems for gynecomastia into a grading system (American Society of Plastic Surgeons, Practice Parameters: Gynecomastia. 2004 [cited 2010]):
- **Grade I:** Small breast enlargement with localized button of tissue that is concentric around the areola
- **Grade II:** Moderate breast enlargement exceeding areola boundaries with edges that are indistinct from the chest
- **Grade III:** Moderate breast enlargement exceeding areola boundaries with edges that are distinct from the chest with skin redundancy present
- **Grade IV:** Marked breast enlargement with skin redundancy and feminization of the breast

(9)
The goal of surgical correction is to restore the normal male contour with minimal scarring, which can be accomplished in a variety of ways: by simple excision of breast tissue perhaps with removal of some subcutaneous fat or, in more advanced cases, subcutaneous mastectomy with resection of redundant skin (Johnson and Murad, Mayo Clin Proc 2009; 84(11): 1010-1015; Ratnam, Aesthet Surg J 2009; 29(1): 26-31; American Society of Plastic Surgeons, Practice Parameters: Gynecomastia. 2004 [cited 2010]; Simon et al., Plast Reconstr Surg 1973; 51(1): 48-52). Subcutaneous mastectomy, although generally reserved for higher grades of gynecomastia, may be appropriate for symptomatic gynecomastia when simple excision of breast tissue is deemed not adequate. Minimally invasive

procedures (e.g., laser therapy, mammotome, RFA) are still considered investigational (Devalia and Layer, Surgeon 2009; 7(2): 114-119).

(10)

Bilateral mammography and US are helpful in the evaluation of gynecomastia and are used as adjuncts to PE. These imaging modalities can distinguish true breast tissue from adipose tissue, as well as differentiate benign from malignant masses (Devalia and Layer, Surgeon 2009; 7(2): 114-119; Morakkabati-Spitz et al., Radiology 2006; 238(2): 438-445; Wise et al., J Am Coll Surg 2005; 200(2): 255-269).

(11)

Medical conditions associated with gynecomastia include hypogonadism, hyperthyroidism, renal disease, malnutrition, cirrhosis or liver disease, testicular or prostate tumors, Klinefelter's syndrome, and XXY males. Attempts should be made to address these underlying causes of gynecomastia prior to considering surgical resection.

(12)

Various medications have been used to treat gynecomastia. Medical treatment for gynecomastia involves blocking estrogen effects in the breast tissue using antiestrogens (e.g., tamoxifen), decreasing estrogen production using aromatase inhibitors (e.g., testactolone), or giving androgens (Narula and Carlson, Endocrinol Metab Clin North Am 2007; 36(2): 497-519; Hanavadi et al., Breast 2006; 15(2): 276-280). While tamoxifen is not approved by the FDA for the treatment of gynecomastia, it has been well studied and does reduce breast pain and swelling. Other medications are used less often, and there is little evidence to support their use (Johnson and Murad, Mayo Clin Proc 2009; 84(11): 1010-1015). Gynecomastia that has been present for longer than 1 year and is fibrotic does not generally regress spontaneously or resolve with medication (Braunstein, N Engl J Med 2007; 357(12): 1229-1237).

(13)

An integral component in the evaluation of gynecomastia is recognizing and discontinuing any drugs that can cause the disorder. Contributory medications should be discontinued or changed to an alternative medication if possible prior to surgical treatment, as the problem may recur after surgery if the drugs are continued. Medications that can cause breast enlargement include certain hormones, chemotherapeutic agents, psychoactive drugs, antibiotics, and antiulcer drugs, as well as drugs of abuse (e.g., marijuana, heroin, amphetamines, anabolic steroids) (Johnson and Murad, Mayo Clin Proc 2009; 84(11): 1010-1015; Cuculi et al., CMAJ 2007; 176(5): 620; Narula and Carlson, Endocrinol Metab Clin North Am 2007; 36(2): 497-519).

ICD-9: 85.31, 85.32, 85.34, 85.36
ICD-10-PCS: 0HBT0ZZ, 0HBT3ZZ, 0HBU0ZZ, 0HBU3ZZ, 0HBV0ZZ, 0HBV3ZZ
CPT®: 19300, 19304, 19318