

**Subject: Hysterectomy**  
**Number: 0314**

**Effective Date: 4/15/2005**  
**Revision Date: 4/15/2006, 4/15/2007**

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## **INSTRUCTIONS FOR USE**

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**Hysterectomy, with or without oophorectomy, is considered medically necessary for the following indications/conditions:**

- uterine leiomyomata (fibroids) when **ALL** of the following medical necessity criteria are met:
  - significant size (i.e., fibroids that have enlarged the uterus to  $\geq$  12 weeks' gestational size (i.e., at least 14 cm in one dimension as measured by transvaginal ultrasound [US])
  - significant symptoms, as indicated by **ANY ONE** of the following:
    - recurrent profuse bleeding lasting longer than seven days or repetitive periods at less than 21-day intervals, in the absence of other remediable pathology after completion of an appropriate evaluation (e.g., ultrasound, endometrial biopsy, sonohysterogram, hysteroscopy, hysterosalpingogram, or Dilation & Curettage [D&C])
    - anemia due to chronic uterine bleeding
    - failure of symptoms to respond to uterine artery embolization (UAE), hysteroscopic resection of submucosal fibroid or endometrial ablation
    - chronic lower abdominal or pelvic pain, low back pressure, rectal pressure or bowel dysfunction for which no other cause can be found
    - urinary symptoms (e.g., frequent urination) found on evaluation to be due to mass pressure effect and not to intercurrent infection or other etiology
- abnormal (premenopausal) uterine bleeding with **ALL** of the following:
  - bleeding is recurrent (i.e., lasting longer than seven days or repetitive periods at less than 21-day intervals) and unresponsive to medical management, including at least a three-month trial of hormonal manipulation unless contraindicated or not tolerated
  - no evidence of other remediable pathology on diagnostic evaluation of the endometrium completed within the last 24 months by endometrial biopsy or D&C
  - no evidence of other remediable pathology on diagnostic imaging of uterine cavity by US, sonohysterogram, hysteroscopy, hysterosalpingogram
  - alternative therapeutic approaches (e.g., endometrial ablation) have been given careful consideration
- chronic pelvic pain when **ALL** of the following criteria have been met:

- persistent pain for more than six months that impairs the patient's ability to complete her usual daily activities and is unresponsive to analgesics or anti-inflammatory agents, unless these medications are contraindicated or not tolerated
  - nongynecological sources of pelvic pain (e.g., gastrointestinal, musculoskeletal, psychological, psychosexual and/or urinary) have been excluded
  - no gynecological cause for the pain has been determined after careful evaluation, including a laparoscopic evaluation performed within the past 24 months
- chronic pelvic inflammatory disease that is unresponsive to appropriate medical management
  - recurrent, high-grade squamous intraepithelial neoplasia (HGSIL), following failure of conservative surgical therapy (e.g., loop electrosurgical excision procedure [LEEP] or cold knife cone)
  - symptomatic pelvic relaxation when **BOTH** of the following are present:
    - second-degree or greater uterine prolapse
    - failure, intolerance, contraindication to, or patient unacceptance of available nonsurgical options such as the use of a pessary
  - when performed in conjunction with laparotomy for adnexal pathology when malignancy is suspected
  - cervical, ovarian or endometrial cancer
  - endometrial hyperplasia with atypia, as demonstrated on endometrial biopsy or D&C, **WITH** failure, contraindication or intolerance (includes patient unacceptance) of hormonal manipulation
  - endometriosis, when **ALL** of the following medical necessity criteria are met:
    - a histological or surgical diagnosis of endometriosis made within the past five years
    - persistent pain for more than six months causing impairment of the patient's ability to participate in her normal daily activities
    - failure, contraindication or intolerance of medical management, including danazol, lupron or other gonadotropin-releasing hormone (GnRH) agonist, oral contraceptives or progestin therapy
    - where applicable, the failure of other appropriate surgical measures to control symptoms

**Prophylactic hysterectomy for hereditary nonpolyposis colorectal cancer (HNPCC) is considered medically necessary after appropriate counseling.**

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## General Background

Hysterectomy is the most common nonobstetric surgical procedure performed on women in the United States (National Center for Health Statistics, 1992). Approximately 600,000 American women undergo hysterectomy every year, and by the age of 60, one out of every three women in the United States will have had a hysterectomy. Hysterectomies are most often performed electively for abnormal uterine bleeding or other non-life-threatening indications. Hysterectomy rates vary by region, with women in the Northeast having the lowest rate and women in the South having the highest hysterectomy rate. Hysterectomy may be performed by either a vaginal or an abdominal approach. For women who require the procedure, the appropriate route of surgery is determined by anatomical factors, the type of pathology expected, patient preference and physician experience and training (Parker, 2004).

The Maine Women's Health Study was a prospective cohort study of 418 women ages 25–50 years undergoing hysterectomy for any nonmalignant condition. Symptoms and quality of life were studied at one year after intervention for patients who underwent hysterectomy compared to those who elected

nonsurgical management (medical therapy) for leiomyomas, abnormal uterine bleeding, and chronic pelvic pain. Among patients in the nonsurgical treatment group, there were some improvements in symptoms and quality of life. However, 25% of the patients with abnormal uterine bleeding and 50% of the patients with pelvic pain elected to have a hysterectomy in the future. In further studies of this group using multivariate logistic regression analysis, hysterectomy was the single most common factor associated with a good outcome at one year. In a related prospective study of patients who underwent hysterectomy for all benign diagnoses, significant improvement was found in symptoms and quality of life at one year (Carlson, et al., 1994).

### **Surgical Techniques**

**Total Abdominal Hysterectomy (TAH):** TAH (with or without salpingo-oophorectomy) is the most commonly performed hysterectomy. Both the uterine fundus and the cervix are removed at the cervico-vaginal junction. The entire uterus, ovaries and fallopian tubes are removed. It may be performed through either a transverse or a vertical abdominal incision, depending on the indications for the procedure and the size of the uterus. This is the procedure of choice for most uterine and ovarian cancers, endometriosis, pelvic pain, large fibroid uteri in which conservation of the cervix is not desired and conditions in which evaluation of the full pelvis and abdomen is required (e.g., pelvic masses or adnexal masses of unknown diagnosis).

**Radical Hysterectomy:** Radical hysterectomy is a procedure in which the parametrial tissue and the upper vagina are removed in conjunction with the fundus and the cervix. It is primarily indicated in the treatment of early-stage cervical cancer. It carries with it a greater risk for bowel and bladder dysfunction, ureteral injury and subsequent urinary fistula.

**Supracervical Hysterectomy:** Supracervical hysterectomy can be performed either abdominally or laparoscopically so that conservation of the cervix may be assured. The fundus of the uterus is removed to the level below the uterine vessels, and the cervix is conserved. Although it is rare, a small area of endometrium may be retained in the cervical stump, leading to monthly menses, and there may be a long-term risk for endometrial cancer even after hysterectomy. This procedure is indicated for the patient who desires to keep her cervix for its potential role in sexual function, and who does not have a contraindication that would preclude her from keeping it (such as cancer or a history of cervical dysplasia). It is also indicated for the patient in whom the surgical procedure would be made safer by conservation of the cervix (such as with obliteration of the cul-de-sac because of advanced endometriosis) and in whom there is no contraindication to its retention. Advantages of this procedure include the greater ease and shorter time required. It is often the preferred surgery for emergency and Cesarean hysterectomies. Retention of the cervix may also result in less vaginal prolapse because of better vaginal support.

**Vaginal Hysterectomy:** Vaginal hysterectomy is performed entirely through the vagina. The most common indications include uterine prolapse or benign or premalignant conditions (e.g., endometrial hyperplasia or cervical dysplasia) that do not result in unusually large uteri and are not likely to result in significant intra-abdominal adhesions and in which exploration of the upper abdomen is nonessential. Advantages of this procedure are the absence of an abdominal scar, the tendency for a quicker recovery, and a shorter hospital stay. Physical requirements for the procedure include the ability to lie on one's back with legs in stirrups for a prolonged time, a relatively small and mobile uterus and adequate room in the vagina in which to operate. Thus, for women who have never had children or who are virginal, this option may not be possible. Experienced surgeons can sometimes remove larger uteri with this approach through coring or by removing the uterus in parts.

**Laparoscopy-Assisted Vaginal Hysterectomy (LAVH):** LAVH combines a vaginal approach with a laparoscopic abdominal approach. This may be appropriate for patients in whom evaluation of the abdomen is indicated (for instance, for grade 1 endometrial cancer), or in whom removal of the ovaries is desired. Although this procedure has the advantages of smaller abdominal scars and shorter hospital stays, many studies (Dorsey, et al., 1996) show it to have higher rates of complication, longer operative times, and higher costs than simple abdominal or simple vaginal hysterectomy. Appropriate case selection and high surgical volume are probably the two leading means of ensuring good outcomes. In general, patients should meet the same physical requirements as for simple vaginal hysterectomy, and they should be at low-risk for laparoscopic complication (no history suggestive of the formation of

abdominal adhesions, normal weight range and no large pelvic masses). If there is uncertainty about a patient, but upper abdominal access is necessary, laparotomy with abdominal hysterectomy may be the procedure of choice.

According to the American College of Obstetricians and Gynecologists (ACOG) committee opinion on the use of LAVH, prospective randomized trials demonstrate that LAVH is associated with faster recovery, less postoperative pain and similar complication rates when compared to TAH. The position further states that the technique used for hysterectomy should be dictated by the indication for the surgery, patient characteristics, and patient preference. However, most patients requiring hysterectomy should be offered the vaginal approach when technically feasible and medically appropriate (ACOG, 2005).

**Total Laparoscopic Hysterectomy (TLH):** TLH involves the removal of the entire uterus and cervix through a small abdominal incision under laparoscopic guidance. The indications for TLH include benign gynecological conditions such as fibroids, endometriosis and abnormal uterine bleeding. The procedure may also be performed for malignant indications such as early endometrial cancer (Mettler, et al., 2005). TLH requires a high degree of surgical skill and is done by a limited proportion of gynecologists. In general, it has been reported that minimally invasive procedures take longer to perform; however, estimated blood loss and patient recovery time are typically less.

A number of studies in the literature have compared TLH to various hysterectomy procedures for the treatment of benign and malignant gynecological conditions. Ghezzi et al. (2005) compared TLH and LAVH for the treatment of endometrial cancer in a randomized clinical trial. No difference was found in the postoperative complication rate between women undergoing LAVH (24.3%) and those who had TLH (17.1%). The investigators concluded that both LAVH and TLH can be performed successfully to manage endometrial cancer, with similar surgical outcomes. It was noted that obese patients benefit more from TLH than from LAVH in terms of shorter operating time.

The EVALUATE hysterectomy trial was a multicenter randomized trial (n=1380) comparing abdominal, vaginal and laparoscopic methods of hysterectomy. Garry et al. (2004) found that laparoscopic hysterectomy took longer to perform and was associated with a significantly higher risk of major complications than abdominal hysterectomy. However, patients who underwent laparoscopic hysterectomy were reported to have less postoperative pain, quicker recovery and better short-term quality-of-life scores after surgery than those who had abdominal hysterectomy.

The National Institute for Clinical Excellence (NICE) issued provisional recommendations for laparoscopic hysterectomy in 2004. According to NICE, the available evidence on the safety of TLH was not adequate to support the use of this procedure “without special arrangements for consent and for audit or research” (NICE, 2004). The consultation document has not been updated with the results of more recent studies. No official guidance on laparoscopic hysterectomy procedures has since been published.

Riberio and colleagues (2003) randomized 60 women to undergo TAH (n=20), vaginal hysterectomy (n=20), or laparoscopic hysterectomy (n=20). It was reported that vaginal hysterectomy produces better results in terms of operative time and inflammatory response when compared to TAH and laparoscopic hysterectomy. However, in the opinion of the authors, laparoscopic hysterectomy showed clear advantages over abdominal hysterectomy and should be considered when the vaginal approach is unfeasible.

An RCT (n=102) conducted by Perino et al. (1999) reported operating times for TLH to be comparable to TAH in a hospital where operators were experienced in endoscopic surgery. The mean length of hospital stay was also found to be significantly shorter for TLH patients ( $p \leq 0.001$ ).

Several retrospective comparative studies and case series have also provided evidence that TLH is technically feasible and can be performed safely in the hands of surgeons who are experienced in operative laparoscopy (Seracchioli, et al., 2002; Obermair, et al., 2005; O’Hanlan, et al., 2005; Hoffman, et al., 2005; Ramirez, et al., 2006).

A Cochrane review by Johnson et al. (2006) assessed the most appropriate surgical approach to hysterectomy for benign disease. A total of 27 trials with 3643 subjects were included. Studies evaluated

abdominal, vaginal and laparoscopic hysterectomies. Laparoscopic hysterectomy was further subdivided into three categories: LAVH, laparoscopic hysterectomy where the laparoscopic procedures include uterine artery ligation, and TLH. It was concluded that when technically feasible, vaginal hysterectomy should be performed in preference to TAH because of more rapid recovery and fewer febrile episodes postoperatively. Where a vaginal hysterectomy is not possible, laparoscopic hysterectomy has some advantages over TAH (e.g., less operative blood-loss, more rapid recovery, fewer febrile episodes and wound or abdominal wall infections), but these are offset by longer operating time and more urinary tract (i.e., bladder or ureter) injuries. No advantages of laparoscopic hysterectomy over vaginal hysterectomy could be found, and laparoscopic hysterectomy procedures took longer. Of the three subcategories of LH, there are more randomized control trial (RCT) data for LAVH and laparoscopic hysterectomy than for TLH, the latter being the most recently introduced approach to hysterectomy. The surgical approach to hysterectomy should be decided by a woman in discussion with her surgeon in light of the relative benefits and hazards (Johnson, et al., 2006).

There is sufficient evidence in the form of RCTs, comparative studies, and case series to support the use of TLH as a treatment option for gynecological conditions. A disadvantage associated with TLH is a higher rate of complications (e.g., bowel, bladder, or urinary tract trauma). Advantages to the procedure include significantly less postoperative pain and shorter hospital stay when compared to abdominal hysterectomy.

In a recent review article, Brill (2006) stated that the final decision by a surgeon to perform a certain method of hysterectomy usually reflects the surgeon's experience and level of comfort with a particular surgical approach in the context of the patient's condition and indication for surgery. All reasonable alternatives should be discussed, and the surgical procedure selected should minimize the risk of complications (Brill, 2006).

### **Indications for Hysterectomy**

The most common indicator for hysterectomy remains uterine leiomyoma (fibroids) (60%), followed by pelvic relaxation (11%), pain (9%), and bleeding (8%). Cancer accounts for roughly 10% of the hysterectomies performed, and endometrial hyperplasia (a premalignant condition) accounts for 2% (Broder, 2000).

**Leiomyoma (Fibroids):** Uterine fibroids or leiomyomata are benign tumors of muscle and connective tissue that develop within the wall of the uterus. Fibroids are the end result of many factors interacting with each other. These factors could be genetic, hormonal, environmental, or a combination of these. Fibroids may grow as a single tumor or in clusters. A single fibroid can be smaller than one inch across or can grow to more than eight inches across. A bunch or cluster of fibroids can also vary in size. It is generally accepted that the size of a non-pregnant uterus ranges from 8 cm x 4 cm x 4 cm to 12 cm. A 10-week gestational size uterus measures 12 cm in length, and a 12-week size uterus measures approximately 14 cm or greater in length (Margulies and Miller, 2001). Most fibroids grow within the wall of the uterus. Fibroids are categorized into four groups on the basis of where they grow:

- Submucosal fibroids grow just underneath the uterine lining and are commonly associated with miscarriage and bleeding disorders (O'Neill, 2003).
- Intramural fibroids grow between the muscles of the uterus.
- Subserosal fibroids grow on the outside of the uterus.
- Pedunculated fibroids hang from a long stalk attached to the outside of the uterus.

Fibroids can contribute to symptoms related to an enlarging pelvic mass (e.g., urinary frequency or constipation). Many women do not feel any symptoms with uterine fibroids, but fibroids may cause the following symptoms:

- heavy bleeding or painful periods
- bleeding between periods
- feeling "full" in the lower abdomen, sometimes called pelvic pressure
- increased urination
- pain during sex

- lower back pain
- noncyclic pelvic pain
- reproductive problems such as infertility, multiple miscarriages and early onset of labor during pregnancy

A transvaginal or pelvic ultrasound may be performed to confirm the findings of uterine fibroids. In addition, dilatation and curettage or pelvic laparoscopy may be necessary to rule out other potentially malignant conditions.

Fibroids may cause infertility because they interfere with conception or implantation. They may cause premature delivery because of decreased area within the uterine cavity. Severe pain or excessively heavy bleeding with fibroids may necessitate emergency surgery. Rarely, malignant changes may occur. However, these usually take place in postmenopausal women. The most common warning sign is the rapid enlargement of a fibroid, and definitive diagnosis is usually not made until the time of surgery.

**Abnormal Uterine Bleeding:** Abnormal or dysfunctional uterine bleeding (DUB) is another common indication for a hysterectomy. In women of childbearing age, a history, physical examination and laboratory evaluation may enable the physician to rule out causes such as pregnancy and pregnancy-related disorders, medications, iatrogenic causes, systemic conditions and obvious genital tract pathology. DUB (i.e., anovulatory and ovulatory) is diagnosed by exclusion of these causes.

In women of childbearing age, abnormal uterine bleeding includes any change in menstrual period frequency or duration or amount of flow, as well as bleeding between cycles. Amenorrhea is defined as the cessation of menses for six months or more in nonmenopausal women. In postmenopausal women, abnormal uterine bleeding includes vaginal bleeding 12 months or more after the cessation of menses, or unpredictable bleeding in postmenopausal women who have been receiving hormone therapy for 12 months or more.

Other terms related to abnormal uterine bleeding include:

- menorrhagia (i.e., excessive menstruation)
- menometrorrhagia (i.e., excessive uterine bleeding at and between menstrual periods)
- metrorrhagia (i.e., uterine bleeding occurring at irregular intervals)
- polymenorrhea (i.e., abnormally frequent menstruation)

Medical management of anovulatory DUB may include oral contraceptives and cyclic progestins, as well as a combination of various oral and injectable estrogens and progestins. Surgical management may include hysterectomy or less invasive, uterus-sparing procedures, such as endometrial ablation. According to the literature, 25% of gynecological surgeries are related to abnormal uterine bleeding (Albers, 2004). Acute bleeding is best controlled with the use of high-dose parenteral estrogen. Estrogens (premarin) are highly effective in controlling uterine bleeding. The immediate action works by creating small vessel hemostasis through a direct effect on clotting, including increasing production of fibrinogen, Factor V and IX activity, and platelet aggregation. A curettage or thorough endometrial aspiration is indicated for women over the age of 35 who have persistent abnormal bleeding or for women with bleeding that is sufficiently severe to produce anemia.

For the woman of reproductive age, long-term therapy depends on whether she requires contraception, induction of ovulation, or treatment of DUB alone. Oral contraceptives or medroxyprogesterone (MPA) can be administered, as stated above, monthly for at least six months, while oral contraceptives and clomiphene citrate are used for the other indications. For the perimenopausal woman who characteristically has lower amounts of circulating estrogen, use of cyclic MPA alone is frequently not curative. In these women, abnormal bleeding is best treated by low-dose oral contraceptives or a combination of estrogen and progestin.

The most difficult management of DUB is treatment of ovulatory women with chronic menorrhagia. For these women, nonsteroidal anti-inflammatory drugs (NSAIDs), progestins, oral contraceptives, danazol, and gonadotropin-releasing hormone (GnRH) analogues are all useful therapeutic modalities. A

combination of two or more of these agents is often required to obviate the need for endometrial ablation or hysterectomy.

**Pelvic Pain:** Chronic pelvic pain (CPP) accounts for approximately 9% of all hysterectomies performed. Hysterectomy should be reserved for patients who have failed conservative therapy. Although no randomized prospective studies have assessed success rates of hysterectomy for relief of CPP, a prospective study by Stovall et al. (1990) reported a 75% cure rate at six months in women who had a hysterectomy for central pelvic pain.

Dysmenorrhea is perhaps the most common example of recurrent pelvic pain and is defined as a painful cramping sensation in the lower abdomen, often accompanied by other symptoms, such as sweating, tachycardia, headaches, nausea, vomiting, diarrhea, and tremulousness. All these symptoms can occur just before or during the menses. Primary dysmenorrhea begins at or shortly after menarche, and is usually not accompanied by pelvic pathologic conditions. Secondary dysmenorrhea arises later and usually is associated with other pelvic conditions.

In addition, the following may be responsible for recurrent or persistent pelvic pain: incompletely treated pelvic infections, recurrent pelvic infections, endometriosis, and possibly postoperative pelvic adhesions, as well as diseases of the urinary tract and bowel.

Patients presenting with CPP should have an adequate workup. In most cases, this would include a laparoscopic examination, with emphasis on the effects of previous operations, infections and injuries. A complete pelvic examination should be carried out. An evaluation of the urinary, gastrointestinal and musculoskeletal systems should be performed to identify other possible sources of pelvic pain. Cervical cultures for gonococcus and chlamydia, as well as a Papanicolaou (Pap) smear, are appropriate.

Some women with CPP also have associated psychosocial problems such as depression, somatization, narcotic dependency, or a history of physical and sexual abuse (Lifford and Barbieri, 2002). Published evidence suggests a significant association of physical and sexual abuse with various chronic pain disorders. Studies have reported that 40–50% of women with CPP have a history of abuse. It is unclear whether physical or sexual abuse specifically causes CPP, and there is no established mechanism by which abuse might lead to the development of CPP. It has been suggested that abuse may result in biophysical changes. It also has been suggested that chronic or traumatic stimulation, especially in the pelvic or abdominal region, increases sensitivity, resulting in persistent pain (ACOG, 2004). It is important that the physician not only determine the specific nature of the pain itself, but also acquire a good understanding of the patient's basic physical, mental and social status to determine what factors may be influencing the patient's symptom complex.

The ACOG guidelines for CPP state that the addition of psychotherapy to medical treatment of CPP should be considered, as the combination appears to improve response over that of medical treatment alone. The guidelines also state that hysterectomy can be considered an effective treatment that results in pain relief for 75–95% of women who have CPP associated with reproductive tract symptoms (ACOG, 2004).

**Cervical Dysplasia:** Dysplasia is a traditional term used to describe varying degrees of cervical intraepithelial neoplasia. The Pap smear has been used widely for several years to screen women for malignant and premalignant cervical dysplasia or disease. Numerous classifications have been used to describe the Pap smear results. One classification used for many years is the Bethesda System, which was based on a conference sponsored by the National Institutes of Health (NIH) in 1988. The results may be mild (low-grade), involving approximately one-third of the epithelium (cervical intraepithelial neoplasia [CIN] I); moderate, involving approximately two-thirds of the epithelium (CIN II); or severe (high-grade), involving the full thickness of the epithelium (CIN III).

Some of the major factors believed to be related to the development of cervical dysplasia include beginning intercourse at an early age, having multiple sexual partners, being infected with a sexually transmitted disease (STD), using oral contraceptives, smoking cigarettes and having prior radiation exposure.

Hysterectomy is indicated for high-grade (CIN III) squamous intraepithelial neoplasia (HGSIL), following failure of conservative surgical therapy in conjunction with no desire for childbearing.

**Uterine Prolapse (Descensus, Procidencia):** Descensus of the uterus and cervix into or through the barrel of the vagina is associated with injuries of the endopelvic fascia, including the cardinal and uterosacral ligaments, as well as injury to or relaxation of the pelvic floor muscles, particularly the levator ani muscles. Occasionally, prolapse is the result of increased intra-abdominal pressure, such as with ascites or of large pelvic or intra-abdominal tumors superimposed on poor pelvic supports. In some instances, sacral nerve disorders, especially injuries to S1-S4, or diabetic neuropathy may be responsible. Major symptoms noted by patients with descensus are a feeling of heaviness, fullness or falling out in the perineal area. In cases where the cervix and uterus are low in the vaginal canal, the cervix may be seen protruding from the introitus, giving the patient the impression that a tumor is bulging out of her vagina.

A prolapse into the upper barrel of the vagina is called first degree. If the prolapse is through the vaginal barrel to the region of the introitus, it is second degree. If the cervix and uterus prolapse out through the introitus, it is called third degree or total. Because prolapse almost always is related to anterior and posterior vaginal wall relaxation, symptoms that are reported for cystocele and rectocele may be present as well. Medical management of such conditions involves the use of a pessary, usually of the Smith-Hodge, donut, cube or inflatable variety. These require the replacement of the uterus and cervix to their usual position in the pelvis and then the institution of support using one of these devices.

Operative repair for prolapse of the uterus and cervix generally involves a vaginal hysterectomy with anterior and posterior colporrhaphy. In some cases, a vaginal hysterectomy is not advisable. These circumstances include previous intra-abdominal operation for an inflammatory process, such as endometriosis or pelvic inflammatory disease. Where such is the case, an abdominal hysterectomy may be performed, followed by a vaginal anterior and posterior colporrhaphy.

**Adnexal Mass:** Adnexal mass refers not only to ovarian abnormalities but to masses originating in the fallopian tube, ovary, broad ligament, and bowel, as well as to uterine masses that lateralize (Scott, 2003). Five to ten percent of all women in the United States will undergo surgical evaluation for an adnexal mass; of these, up to one-fifth will have ovarian cancer. Thus, the appropriate evaluation is important and includes a complete history, physical examination, and radiological studies (Scott, 2003). Most ovarian malignancies occur in the postmenopausal group.

Suspicion of an adnexal mass may arise as a result of either a patient's symptoms or suspicious findings during a pelvic examination. In these cases, radiological imaging is usually the next step in the diagnostic evaluation. Adnexal masses that have solid components, inner wall papillations, or nodularity on imaging would require surgical intervention (Scott, 2003).

**Endometrial Cancer:** Endometrial cancer is the fourth most common cancer in women and is the most common invasive gynecological cancer in U.S. women, with more than 40,000 new cases occurring in 2005 (American Cancer Society, 2005). Adenocarcinoma of the endometrium is mainly a malignancy of postmenopausal women and is increasingly virulent with advancing age. Peak age at diagnosis is between the ages of 50 and 65. Approximately 25% of all cases of endometrial carcinoma are diagnosed in premenopausal women, and only 5% are diagnosed in women younger than age 40 (Scott, 2003).

There are two types of endometrial cancers, designated type I and type II. Type I endometrial cancer is estrogen-dependent and is thought to progress typically from hyperplasia to cancer. This type of malignancy typically occurs in younger perimenopausal women with a history of exposure to unopposed estrogen. These tumors tend to arise in areas of hyperplasia, to be well differentiated and to be associated with a more favorable prognosis. Type II endometrial cancer occurs in older women without estrogen stimulation of the endometrium, is not often associated with endometrial hyperplasia and tends to be more commonly associated with poorly differentiated cancer or those of unusual histological type (Scott, 2003). Risk factors for endometrial cancer include:

- long-term unopposed estrogen exposure of either endogenous (e.g., obesity, nulliparity, late menopause) or exogenous origin

- estrogen-secreting tumors, such as granulosa cell tumors
- a history of pelvic irradiation
- a history of breast or ovarian cancer
- use of tamoxifen

According to the literature, oral contraceptives and cigarette smoking may decrease the risk of developing endometrial cancer.

There are no accepted routine screening methods for detecting endometrial cancer in asymptomatic women or in women at increased risk. Even though a routine Pap smear cannot be relied on as a screen for endometrial cancer, this type of malignancy should be suspected in any nonpregnant woman with atypical endometrial cells or in any postmenopausal woman with normal endometrial cells on a Pap smear (Scott, 2003). Abnormal uterine bleeding is the most common initial symptom of endometrial cancer. Any bleeding in a postmenopausal woman should be evaluated promptly. It is recommended that perimenopausal women with abnormal bleeding undergo an office endometrial biopsy. An endocervical curettage (ECC) should usually be performed in the evaluation of postmenopausal bleeding to rule out an endocervical carcinoma as the etiology. Transvaginal ultrasonography for evaluating the thickness of the endometrium may also be performed in patients with postmenopausal bleeding. If endometrial adenocarcinoma is diagnosed, further evaluation of the patient is necessary prior to deciding on the therapeutic approach. This may include a physical exam, chest x-ray, and routine labs.

Endometrial cancer is currently staged according to the International Federation of Gynecology and Obstetrics (FIGO) staging system. The recommendation is for all medically operable patients with clinical stage I disease, regardless of tumor grade, to undergo an extrafascial TAH and bilateral salpingo-oophorectomy for both staging and therapeutic purposes. A radical hysterectomy may be appropriate in certain circumstances in which the disease is known to involve the cervix or parametrium (Scott, 2003). According to the literature, it has been thought that a history of endometrial cancer, even successfully treated, was an absolute contraindication to estrogen replacement therapy (ERT), because adenocarcinoma of the endometrium is considered an estrogen-dependent neoplasm. There are no scientific data in the literature to support that ERT is dangerous for patients who have had a hysterectomy for endometrial cancer. The body of evidence in the peer-reviewed literature is increasingly in support of the value of ERT in decreasing morbidity and mortality from heart disease, strokes and osteoporosis (American College of Obstetricians and Gynecologists [ACOG], 2003; Scott, 2003).

In a Committee Opinion in August 2003, ACOG concluded that there are no definitive data to support specific recommendations regarding ERT for women previously treated for endometrial cancer. The opinion states that estrogens could be used for the same indications as for any other woman, except that the selection of appropriate candidates should be based on both prognostic indicators and the risk that a patient is willing to assume. The gynecological practice committee, due to the paucity of data, could not evaluate the need for progestational agents in addition to estrogens (ACOG, 2003; Scott, 2003).

**Endometrial Hyperplasia:** Endometrial hyperplasia is generally considered a precursor to endometrial cancer. The condition occurs during periods of long-term unopposed estrogen stimulation, such as anovulation, particularly around the time of menopause. The World Health Organization (WHO) identifies four categories of endometrial hyperplasia according to their premalignant potential: simple, complex, simple with atypia, and complex with atypia. Prospective studies have demonstrated a cumulative incidence of carcinoma of 10–30% among patients with atypical endometrial hyperplasia (Primary Care Medicine, 2001).

The risk of endometrial cancer increases with dosage and duration of estrogen use. Progestins prevent the development of endometrial hyperplasia that is otherwise associated with unopposed estrogen use. The incidence of atypical or adenomatous endometrial hyperplasia decreases from 35% to 1% with progestin use. At least five studies have examined the effect of estrogen plus progestin therapy on endometrial cancer risk, and none found a significant increase. This absence of risk with progestin has been confirmed by the Women's Health Initiative (WHI) trial.

The largest randomized controlled trial (RCT) of combined hormone therapy (HT) was the WHI study (n=16,608). This study found that, after an average follow-up of 5.6 years, women randomized to combined HT had a hazard ratio for endometrial cancer of 0.81 (95% confidence interval [CI] = 0.48–1.36) compared to women randomized to placebo. This confidence interval is wide but is consistent with prior evidence showing no increased risk associated with combined HT use (Anderson, 2003).

There are a limited number of RCTs in the literature that address the histological findings of the endometrium of postmenopausal women who are receiving estrogen replacement. Some randomized, controlled data were provided by the Postmenopausal Estrogen Progestin Interventions (PEPI) Trial (Writing Group for the PEPI Trial, 2003). Results of this three-year, multicenter RCT (n=600) showed that conjugated equine estrogen (CEE) at a dose of 0.625 mg daily was associated with the development of endometrial hyperplasia, which could be prevented by adding medroxyprogesterone acetate (MPA) or micronized progesterone (MP) to the treatment regimen.

Mild complex hyperplasia with atypia often responds to progestin therapy and is an option for those women who are interested in preserving the uterus for childbearing. Three months of progestin therapy is the initial recommended therapy (Stenchever, 2001). Since approximately 25–30% of atypical hyperplasia, which is diagnosed via endometrial biopsy, can potentially progress to endometrial cancer, the suggested treatment is hysterectomy when preservation of the uterus is not desired. The more severe the atypia, the less chance it will reverse itself with hormone therapy.

Several studies have evaluated the correlation between atypical endometrial hyperplasia and endometrial cancer. Shutter and colleagues (2005) reviewed 60 women with a diagnosis of either atypical endometrial hyperplasia (ATHY) or atypical proliferative lesion of the endometrium, suggestive but not diagnostic of atypical endometrial hyperplasia (APL). All patients subsequently received hysterectomy (n=60). Endometrial adenocarcinoma was identified in 48% of the hysterectomy specimens. The authors concluded that there is a high prevalence of underlying endometrial adenocarcinoma among women undergoing hysterectomy for any type of atypical endometrial proliferation.

In a prospective cohort study, Trimble et al. (2006) set out to estimate the prevalence of concurrent carcinoma in 289 women with a biopsy diagnosis of atypical endometrial hyperplasia (AEH). All subjects underwent hysterectomy. The rate of concurrent endometrial carcinoma for analyzed hysterectomy specimens was reported to be 42%. The investigators noted that the significant incidence of concurrent carcinoma should be considered in planning treatment for women with a diagnosis of AEH.

According to the ACOG guidelines for the management of endometrial cancer, atypical endometrial hyperplasia and endometrial cancer should be considered part of a continuum. The diagnosis remains uncertain as long as the uterus is in situ. For women who have completed childbearing, hysterectomy should be recommended for the treatment of atypical endometrial hyperplasia because of the high risk of an underlying cancer. Women who want to maintain fertility may be treated with progestins in an attempt to reverse the lesion (ACOG, 2005).

**Endometriosis:** Endometriosis is the presence and growth of the glands and stroma of the lining of the uterus in an aberrant or heterotopic location. The classic symptoms of endometriosis are cyclic pelvic pain and infertility. However, approximately one-third of patients with endometriosis are asymptomatic, with the disease being discovered incidentally during an abdominal operation or visualized at laparoscopy for an unrelated problem. The classic pelvic finding of endometriosis is a fixed, retroverted uterus, with scarring and tenderness posterior to the uterus.

The diagnosis can be confirmed in most cases by direct laparoscopic visualization of endometriosis with its associated scarring and adhesion formation. In many patients, it is discovered for the first time during an infertility investigation. Biopsy of selected implants gives confirmation of the diagnosis.

The two primary short-term goals in treating endometriosis are the relief of pain and promotion of fertility. The primary long-term goal in the management of endometriosis is attempting to prevent progression or recurrence of the disease process. Most patients should undergo a diagnostic laparoscopy to establish the nature and extent of endometriosis before therapy. However, if other gynecological conditions, such

as chronic pelvic inflammatory disease or neoplasia, have been ruled out, empiric medical therapy for 3–6 months with a GnRH agonist is a reasonable choice.

Treatment of endometriosis can be medical, surgical or a combination of both. The primary goal of the hormonal treatment of endometriosis is relief of pain. Surgical therapy is divided into conservative and definitive operations. Conservative surgery involves the resection or destruction of endometrial implants, lysis of adhesions, and attempts to restore normal pelvic anatomy. Definitive surgery involves hysterectomy, which includes the removal of the ovaries, the uterus and all visible ectopic foci of endometriosis.

**Adenomyosis:** Adenomyosis is caused by the presence of functioning ectopic endometrial tissue in the myometrium. It appears to be most common in women ages 41–50. Adenomyosis occurs in 15–20% of uteri and may be diffuse or focal. The pathogenesis of adenomyosis remains unclear. Common presenting symptoms include menorrhagia, dysmenorrhea and an enlarged, sometimes tender uterus. Pain may be referred to the back and rectum. The presenting symptoms of adenomyosis overlap with those of other common gynecological disorders such as DUB, uterine leiomyomata and endometriosis. There is also a slightly increased rate of endometrial carcinoma in patients with adenomyosis. There is no proven medical treatment for adenomyosis. Hysterectomy is the definitive treatment for women who have completed childbearing.

The standard criterion used in diagnosing adenomyosis is the finding of endometrial glands and stroma more than 2.5 millimeters (mm) from the basalis layer of the endometrium. Attempts have been made to establish the diagnosis preoperatively by transcervical needle biopsy of the myometrium; however, the sensitivity of this testing method is reportedly too low to be of practical clinical value. Adenomyosis is often diagnosed incidentally by histological examination of a hysterectomy specimen. Both ultrasound and magnetic resonance imaging (MRI) are useful to assist in differentiating between adenomyosis and uterine myomas in young women desiring future childbearing. Diagnosing adenomyosis by transvaginal ultrasonography (TVU) has a reported sensitivity of 53–89% and a specificity of 50–89%. In some series, MRI has been reported to be more sensitive (88–93%) with a higher specificity (66–91%) than ultrasonography in the diagnosis of adenomyosis (Stenchever, 2001). The peer-reviewed medical literature suggests that TVU be used as the initial imaging technique in patients suspected of having adenomyosis. MRI may be used as an adjunctive tool to differentiate between adenomyosis and uterine leiomyoma, especially preoperatively in women who desire future fertility.

**Hereditary Nonpolyposis Colorectal Cancer (HNPCC):** HNPCC is one of the four main familial colorectal cancer (CRC) syndromes that have been characterized both clinically and genetically. Genetic susceptibility is responsible for a substantial portion of CRC, and at least 20% of cases occur within familial aggregates.

HNPCC is the most commonly occurring familial CRC syndrome and may account for approximately 5–7% of all CRC. Young age of onset and proximal CRC arising in the setting of solitary or few sessile adenomas typify this condition, but cancers of the endometrium, small bowel, ureter, or renal pelvis are also associated with HNPCC. HNPCC-associated tumors often have specific histopathologic features of marked lymphocytic infiltration, as well as lymphoid aggregation at the tumor margin, and tend to be mucinous and poorly differentiated. Even though the tumors are higher grade, they are often associated with improved survival compared with sporadic CRC.

The International Collaborative Group for HNPCC developed the Amsterdam criteria (AC) as the first set of clinical and family history criteria to consistently identify individuals who might belong to an HNPCC kindred. To be classified as having HNPCC by AC, a kindred should have a minimum of three relatives from two generations affected by CRC; one must be a first-degree relative of the other two, and one of the cancers should have occurred by age 50. Candidates for genetic testing for HNPCC can also be identified by the Bethesda criteria, which are a set of recommendations that encompass and extend the AC by reducing the requirement for two generation kindreds. The Bethesda criteria gives more weight to young-onset colorectal adenomas (< 40 years) or cancer (< 45 years), recognizes the HNPCC-associated tumors other than CRC that may be a marker for HNPCC, and highlights histopathologic characteristics of tumors that have defective deoxyribonucleic acid (DNA) mismatch repair. These recommendations allow

an individual to be considered for genetic testing in the presence of one or more of the following clinical or histologic features:

- multiple HNPCC-associated cancers
- personal history of young-onset CRC or endometrial cancer (age < 45 years)
- personal history of colorectal adenomas (age < 40)
- personal history of young-onset, right-sided CRC (age < 45) with undifferentiated pattern or any location signet-ring CRC
- personal history of CRC and family history of first-degree relative with HNPCC-related cancer, either of which are young-onset (age < 45)

Though the AC require the presence of at least one young-onset CRC to diagnose HNPCC in a kindred, the risk for the development of CRC increases with age. The gradient of CRC risk increases from roughly one-third of DNA mismatch repair defect gene carriers at age 40 to nearly 90% of gene carriers by age 75. Endometrial cancer may be screened for known germline mutation carriers with annual endometrial aspiration biopsy and transvaginal ultrasound beginning at age 25. For at-risk relatives, similar recommendations for endometrial screening may be useful in the setting of an HNPCC kindred in which endometrial cancer has occurred.

Patients with HNPCC who develop colon cancer should be offered an ileorectal anastomosis rather than segmental resection because of the frequency of metachronous polyps and cancer. Though endometrial cancer risk is significantly increased in some HNPCC kindreds, the recent American Gastroenterological Association (AGA) consensus statement on screening for hereditary CRC determined that there is insufficient evidence to recommend for or against prophylactic hysterectomy and oophorectomy in women with HNPCC.

The Cancer Genetics Studies Consortium concluded that, although there were no available data on the efficacy of hysterectomy combined with oophorectomy in the management of HNPCC, it should be offered as an option for prevention of endometrial and ovarian cancer in women known to have HNPCC or to be carriers of HNPCC-associated mutations. Such individuals need thoughtful counseling regarding the risks and benefits of the procedure, as well as options available to them for cancer surveillance and follow-up (Burke, et al., 1997).

### Summary

Hysterectomy is effective in treating a number of gynecological disorders, including symptomatic leiomyoma, abnormal uterine bleeding, endometrial hyperplasia and surgical dysplasia. The procedure may also alleviate symptoms in some women with endometriosis, chronic pelvic pain, pelvic inflammatory disease and pelvic relaxation. Prophylactic hysterectomy with bilateral oophorectomy is recommended for individuals with hereditary nonpolyposis colorectal cancer (HNPCC)-related conditions who have been properly counseled. An appropriate diagnostic evaluation should be performed and alternative treatments considered prior to the recommendation of hysterectomy for any indication.

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## Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**When medically necessary:**

CPT®* Codes	Description
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)
58152	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s); with colpo-urethrocystopexy (eg, Marshall-Marchetti-Krantz, Burch)
58180	Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without

	removal of tube(s), with or without removal of ovary(s)
58200	Total abdominal hysterectomy, including partial vaginectomy, with para-aortic and pelvic lymph node sampling, with or without removal of tube(s), with or without removal of ovary(s)
58210	Radical abdominal hysterectomy, with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy), with or without removal of tube(s), with or without removal of ovary(s)
58240	Pelvic exenteration for gynecologic malignancy, with total abdominal hysterectomy or cervicectomy, with or without removal of tube(s), with or without removal of ovary(s), with removal of bladder and ureteral transplantations, and/or abdominoperineal resection of rectum and colon and colostomy, or any combination thereof
58260	Vaginal hysterectomy, for uterus 250 grams or less
58262	Vaginal hysterectomy, for uterus 250 grams or less; with removal of tube(s), and/or ovary(s)
58263	Vaginal hysterectomy, for uterus 250 grams or less; with removal of tube(s), and/or ovary(s), with repair of enterocele
58267	Vaginal hysterectomy, for uterus 250 grams or less; with colpo-urethrocytopexy (Marshall-Marchetti-Krantz type, Pereyra type) with or without endoscopic control
58270	Vaginal hysterectomy, for uterus 250 grams or less; with repair of enterocele
58275	Vaginal hysterectomy, with total or partial vaginectomy
58280	Vaginal hysterectomy, with total or partial vaginectomy; with repair of enterocele
58285	Vaginal hysterectomy, radical (Schauta type operation)
58290	Vaginal hysterectomy, for uterus greater than 250 grams
58291	Vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s) and/or ovary(s)
58292	Vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s) and/or ovary(s), with repair of enterocele
58293	Vaginal hysterectomy, for uterus greater than 250 grams; with colpo-urethrocytopexy (Marshall-Marchetti-Krantz type, Pereyra type) with or without endoscopic control
58294	Vaginal hysterectomy, for uterus greater than 250 grams; with repair of enterocele
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58548	Laparoscopy, surgical, with radical hysterectomy, with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy), with removal of tube(s) and ovary(s), if performed
58550	Laparoscopy surgical, with vaginal hysterectomy, for uterus 250 grams or less
58552	Laparoscopy surgical, with vaginal hysterectomy, for uterus 250 grams or less with removal of tube(s) and/or ovary(s)
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 grams
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s) and/or ovary(s)
58951	Resection of ovarian, tubal or primary peritoneal malignancy with bilateral salpingo-oophorectomy and omentectomy; with total abdominal hysterectomy, pelvic and limited para-aortic lymphadenectomy
58953	Bilateral salpingo-oophorectomy with omentectomy, total abdominal hysterectomy and radical dissection for debulking;
58954	Bilateral salpingo-oophorectomy with omentectomy, total abdominal hysterectomy and radical dissection for debulking; with pelvic lymphadenectomy

	and limited para-aortic lymphadenectomy
58956	Bilateral salpingo-oophorectomy with total omentectomy, total abdominal hysterectomy for malignancy

<b>HCPCS Codes</b>	<b>Description</b>
S2078	Laparoscopic supracervical hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)

<b>ICD-9-CM Diagnosis Codes</b>	<b>Description</b>
154.0	Malignant neoplasm of rectosigmoid junction
180.0-180.9	Malignant neoplasm of cervix uteri
182.0-182.8	Malignant neoplasm of body of uterus
183.0-183.9	Malignant neoplasm of ovary and other uterine adnexal
198.6	Secondary malignant neoplasm of ovary
218.0-218.9	Uterine leiomyoma
219.0-219.9	Other benign neoplasm of uterus
220	Benign neoplasm of ovary
221.0-221.9	Benign neoplasm of other female genital organs
233.1-233.3	Carcinoma in situ of breast and genitourinary system
456.5	Pelvic varices
614.6	Pelvic peritoneal adhesions, female (postoperative) (postinfection)
617.0-617.9	Endometriosis
618.00-618.9	Genital prolapse
620.0-620.9	Noninflammatory disorders of ovary, fallopian tube, and broad ligament
621.6	Malposition of uterus
622.10	Dysplasia of cervix; unspecified
622.11	Mild dysplasia of cervix
622.12	Moderate dysplasia of cervix
625.0-625.9	Pain and other symptoms associated with female genital organs
626.2	Excessive or frequent menstruation
626.4	Irregular menstrual cycle
626.8	Other disorder of menstruation and other abnormal bleeding from female genital tract
626.9	Unspecified disorder of menstruation and other abnormal bleeding from female genital tract
627.0	Premenopausal menorrhagia
627.1	Postmenopausal bleeding
627.8	Other specified menopausal and postmenopausal disorder
627.9	Unspecified menopausal and postmenopausal disorder
752.3	Other congenital anomaly of uterus
795.00	Abnormal glandular Papanicolaou smear of cervix
795.01	Papanicolaou smear of cervix with atypical squamous cells of undetermined significance (ASC-US)
795.02	Papanicolaou smear of cervix with atypical squamous cells cannot exclude high grade squamous intraepithelial lesion (ASC-H)
795.09	Other abnormal Papanicolaou smear of cervix and cervical HPV

\*Current Procedural Terminology (CPT®) ©2006 American Medical Association: Chicago, IL.

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