Medica

Title: *Management of Benign Uterine Conditions*

This guideline was developed with input from specialists in obstetrics & gynecology and endorsed by the Medical Policy Committee.

Scope and Purpose

The purpose of this guideline is to provide evidence-based information to describe conservative therapies that may delay or prevent the need for hysterectomy and the appropriate indications for various hysterectomy techniques in patients with benign gynecologic conditions after conservative therapies have been found to be either contraindicated or ineffective. This guideline addresses elective hysterectomy for benign gynecologic disease. It does not address emergency hysterectomy (e.g., due to acute hemorrhage or trauma) or hysterectomy due to malignancy.

Definitions

1. **Endometriosis:** Occurrence of endometrial tissue outside the uterus. Foci of endometrial tissue may occur in the fallopian tubes, ovaries, or peritoneum and in other sites in the body outside the uterus.
2. **Genital prolapse** refers to a downward protrusion of an internal organ out of its normal cavity. The term usually applies to protrusion of the uterus or rectum following progressive weakening of the muscles, ligaments, and other supporting tissues around the organ.
3. **Hysterectomy** is generally referred to as the complete removal of the corpus and cervix of the uterus.
4. **Leiomyoma** is a benign tumor of smooth muscle origin, also referred to as a "fibroid." Leiomyomas are considered to be endocrine-dependent lesions. Their growth and size are dependent upon estrogen.
5. **Non-cyclic or anovulatory uterine bleeding** refers to bleeding from the uterine endometrium that is unrelated to cyclical menstrual bleeding. This also referred to as dysfunctional uterine bleeding.

Conservative Approaches

1. The use of any medical or surgical treatment option for the conditions described in this guideline should be based on a complete patient history and physical examination including careful evaluation to assess underlying biochemical abnormalities and/or co-morbidities that may contribute to the condition and to rule out the presence of malignancy.
2. Conservative treatments
   A. Uterine leiomyomas
      1) Asymptomatic leiomyomas that are stable in size require close monitoring by a physician, but no specific treatment.
      2) Treatment of leiomyomas in the presence of symptoms includes:
         a. Medical management (e.g., contraceptive steroids, gonadotropin-releasing hormone (GnRH) agonists)
         b. Abdominal, hysteroscopic or laparoscopic myomectomy
         c. Uterine artery embolization in carefully selected patients who wish to retain their uteri.

      Note: Several technologies intended to ablate uterine leiomyomas are currently under study. For more information, refer to Medica coverage policy*, High Intensity Focused Ultrasound (HIFU) and Magnetic Resonance Guided Focused Ultrasound (MRgFUS).*

   B. Endometriosis
      1) Endometriosis may require close monitoring by a physician, but no specific treatment, if few symptoms are present or the extent of the condition is minimal.
      2) Pain and other symptoms associated with endometriosis may be reduced through the use of:
         a. GnRH agonists (short term use)
         b. Oral contraceptives (cyclic or continuous dose)

c. Progestins, including intrauterine progestin
d. Danazol
e. Anti-inflammatory drugs.

3) Surgical interventions include laparoscopic and laparotic resection or ablation.

C. Non-cyclic uterine bleeding not caused by leiomyomas
The patient's condition should be thoroughly assessed (e.g., ultrasound, hysteroscopy, endometrial biopsy, laboratory studies) prior to treatment. Treatments may include:
1) Medical therapy with oral (cyclic or continuous dose), transdermal or transvaginal contraceptives, Levonorgestrel IUD, antifibrinolytic therapy (tranexamic acid).
2) Oral, parenteral (IM), or intrauterine progesterone therapy
3) Endometrial ablation if medical therapy is contraindicated or has failed.

D. Uterine prolapse
1) Pelvic floor exercises
2) Vaginal pessaries

3. Hysterectomy should be considered only after medically appropriate conservative treatments have been explored and proven to be contraindicated or ineffective in treating a specific condition.

Hysterectomy - Background

1. Hysterectomy is one of the most frequently performed major surgical procedures among non-pregnant women in the U.S., with approximately 600,000 hysterectomies performed annually. There is substantial variation in the overall hysterectomy rate and type of procedure performed depending upon the skill, experience, and preferences of the surgeon, patient-related characteristics, and geographic region. The diagnoses of uterine leiomyoma, endometriosis, and uterine prolapse were the most common reasons reported for hysterectomy and accounted for 73 percent of all hysterectomies performed between 1994 and 1999, according to a study published by the Centers for Disease Control and Prevention.
2. The American College of Obstetrics and Gynecology (ACOG) has concluded that there is insufficient evidence to support hysterectomy for asymptomatic leiomyomas solely to improve detection of adnexal masses, to prevent impairment of renal function or to rule out malignancy. The clinical diagnosis of rapidly growing leiomyomas should not be used as an indication for myomectomy or hysterectomy. Documentation should be completed indicating that the strengths, possible complications, and physiologic consequences of each procedure have been discussed with the patient prior to any type of hysterectomy. If a woman is of childbearing age, documentation should reflect that the patient has clearly indicated that she does not desire future fertility.
3. ACOG states, “the technique used for hysterectomy should be dictated by the indication for the surgery, patient characteristics and patient preference.”

Types of Hysterectomy

1. Types of hysterectomy include the following:
   A. **Supracervical or subtotal hysterectomy.** This procedure includes removal of the fundus of the uterus, leaving the cervix.
   B. **Total hysterectomy** removes the entire uterus, with or without the fallopian tubes and ovaries.
   C. **Radical hysterectomy** removes the uterus, upper vagina, and parametrium. This is generally done, along with removal of pelvic lymph nodes, in the treatment of cancer.
   D. **Modified radical hysterectomy,** also referred to as the TeLinde operation, is an extended hysterectomy in which a portion of the upper vagina is removed, the ureters are exposed and pulled back laterally without dissection from the ureteral bed.
2. Surgical approaches to hysterectomy for benign conditions include:
   A. **Abdominal hysterectomy** involves removal of the uterus through an incision in the abdominal wall.
   B. **Vaginal hysterectomy** removes the uterus through the vagina without making an incision in the wall of the abdomen. Vaginal hysterectomy is also referred to as a colpohysterectomy or vaginohysterectomy.
   C. **Laparoscopic hysterectomy**

   1) The laparoscopic-assisted vaginal hysterectomy (LAVH) combines laparoscopic and vaginal approaches. In the procedure, the ovarian pedicle, broad ligament, and uterosacral ligaments are severed using laparoscopic instruments and the procedure completed through a colpotomy.
   2) A uterine vessel ligation laparoscopic hysterectomy (LH(a)) also combines the laparoscopic and vaginal approaches. In this procedure, the uterine vessels are ligated laparoscopically.
   3) Total laparoscopic hysterectomy, as the name implies, has no vaginal component.
   4) Laparoscopic supracervical hysterectomy (LSH) removes the uterus, but preserves the cervix. The ovaries and fallopian tubes can also be removed in this procedure.
3. Non-abdominal hysterectomy is the preferred approach for benign disease. It is associated with reduced complication rates, shorter length of inpatient stays, and shorter convalescence on average when compared to other approaches.
4. If vaginal hysterectomy is not an option, a laparoscopically-assisted approach may be considered if specific procedures that can be completed with laparoscopy are anticipated prior to the procedure.
   A. ACOG identifies the following additional procedures that can be completed laparoscopically to assist a vaginal hysterectomy when indicated:
      1) Lysis of adhesions
      2) Treatment of endometriosis
      3) Management of uterine leiomyomas that complicate the performance of a vaginal hysterectomy
      4) Ligation of infundipulopelvic ligaments to facilitate difficult ovary removal
      5) Evaluation of pelvic and abdominal cavity before hysterectomy.
   B. Laparoscopic approaches can carry a potential for additional complications when compared with vaginal hysterectomy. These include injury to the urinary tract, bowel, and major blood vessels. Abdominal hysterectomy is indicated if vaginal or laparoscopic approaches are not appropriate or may be unsafe due to the extent of disease outside the uterus, size of the uterus (e.g., greater than 280g), or inadequate vaginal access.
   C. In April 2014, the U.S. Food and Drug Administration (FDA, 2014) issued a warning about laparoscopic power morcellators in women with unsuspected uterine sarcoma, as there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient's likelihood of long –term survival. For this reason, and because there is no reliable method for predicting whether a woman with fibroids may have a uterine sarcoma, the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy or uterine fibroids.
5. The field of robotic surgery is developing rapidly, but experience with this technology is currently limited. Randomized trials comparing robot-assisted surgery with traditional laparoscopic, vaginal or abdominal surgery are needed to evaluate long-term clinical outcomes and cost-effectiveness, as well as to identify the best applications of this technology.
   Note: For more information, refer to Medica reimbursement policy*, Robotic-Assisted Surgery.*

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DOCUMENT HISTORY

Original MPC Endorsement Date	December 2005
Subsequent MPC Endorsement Date(s)	04/2007, 04/2009, 04/2011, 06/2013, 09/2015, 09/2017, 11/2019, 11/2021