

MEDICAL POLICY



**SUBJECT: UTERINE ARTERY OCCLUSION IN
THE TREATMENT OF UTERINE
FIBROIDS**

POLICY NUMBER: 4.01.04

CATEGORY: Technology Assessment

EFFECTIVE DATE: 06/21/00

**REVISED DATE: 05/17/01, 03/21/02, 02/20/03, 02/19/04,
02/17/05, 01/19/06, 01/18/07, 01/17/08,
01/15/09, 01/21/10, 12/16/10, 12/15/11,
12/20/12, 11/21/13**

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- *If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.*
- *Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.*
- *Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.*

POLICY STATEMENT:

I. Uterine artery embolization:

- A. Based upon our criteria and review of the peer-reviewed literature, uterine artery embolization (UAE), with a FDA approved embolic agent, in the treatment of symptomatic uterine fibroids and severe menorrhagia, despite an adequate trial of hormonal therapy when appropriate, has been proven to be medically effective and therefore, a **medically appropriate** treatment option.

Symptomatic uterine fibroids are those that cause acute severe pelvic pain, chronic lower abdominal pain, and/or back or bladder pressure with urinary frequency or urgency not due to urinary tract infection.

- B. UAE is generally not indicated in women who desire future pregnancy unless it is the only reasonable option for those who have failed or are not candidates for hormone therapy or myomectomy; as the results of UAE on ovarian function have not yet been fully determined.

C. **Contraindications** to UAE include:

1. Current pregnancy;
2. Pelvic inflammatory disease or active pelvic infection;
3. Contrast medium allergy when appropriate pretreatment (e.g., administration of steroids, antihistamines) has not been rendered;
4. Uncorrected coagulatory or vascular disorders;
5. Arteriovenous malformation;
6. Severe renal insufficiency;
7. Prior pelvic irradiation;
8. Ovarian, uterine, endometrial or cervical cancers or undiagnosed pelvic mass.

II. Laparoscopic uterine artery occlusion:

Based upon our criteria and review of the peer-reviewed literature, laparoscopic uterine artery occlusion (LUAO) using vascular clips or bipolar coagulation, as a treatment of uterine fibroids, has not been medically proven to be effective and is considered **investigational**.

Refer to Corporate Medical Policy #4.01.09 regarding MRI Guided Focused Ultrasonic Tumor Ablation.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

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DESCRIPTION:

Uterine fibroids, or leiomyomata, are benign proliferations of smooth muscle cells and fibrous connective tissue arising from the uterine muscle tissue. It is estimated that they occur in 20-50% of women of reproductive age. Arterial embolization has been used since the 1960s to control hemorrhage resulting from malignancy, trauma, surgery, and radiation.

Uterine artery embolization (UAE), or uterine fibroid embolization (UFE), involves the insertion of catheters into uterine arteries that give rise to the fibroid(s) and the injection of appropriate embolic agent (e.g., polyvinyl alcohol particles [PVA], gelfoam/gelatin sponge, acrylic microspheres) to permanently seal arterial flow. The cessation of arterial flow to the fibroid causes ischemia and infarction of the fibroid.

“Post embolization syndrome”, characterized by pain, cramping, fever, nausea and/or vomiting, is experienced by most patients. It is usually considered a benign, self-limiting condition and resolves in several days. Some women have experienced cramping and pain up to several weeks with an otherwise uncomplicated recovery.

The risks and complications of UAE include: infection due to ischemia and necrosis of the fibroid, reported incidents of ovarian failure, technical failure due to the inability to catheterize the uterine arteries, exposure to radiocontrast material and focused radiation, and the risk of arterial injuries and/or hematomas.

Other methods of treating uterine fibroids, as an alternative to uterine artery embolization, have recently been under investigation. These methods include laparoscopic occlusion of the uterine arteries using vascular clips or bipolar coagulation.

RATIONALE:

Uterine artery embolization is a surgical procedure and not subject to FDA regulation. The embolic agents utilized in the UAE procedure are considered devices and are regulated by the FDA. The acrylic microspheres are the only embolic agent specifically approved by the FDA for use in UAE, although other agents have been approved for general embolization usage.

Review of the peer-reviewed, published literature regarding fertility and pregnancy outcomes after UAE suggest that successful pregnancy is possible, but that there are higher rates of miscarriage and post-partum hemorrhage compared to women who have not received treatment for intramural fibroids and higher rates of preterm delivery compared to women whose fibroids had been treated by myomectomy.

A practice bulletin, published by the American College of Obstetricians and Gynecologists (ACOG), addresses alternatives to hysterectomy in the management of leiomyomas and replaces a committee opinion addressing UAE that was most recently reaffirmed in 2010. The practice bulletin states based on long- and short-term outcomes, UAE is a safe and effective option for appropriately selected women who wish to retain their uteri. Women who wish to undergo UAE should have a thorough evaluation with an obstetrician–gynecologist to help facilitate optimal collaboration with the interventional radiologists and to ensure the appropriateness of therapy, taking into account the reproductive wishes of the patient. The practice bulletin does not address laparoscopic occlusion of the uterine arteries.

A 2007 Technology Assessment published by the Agency for Healthcare Research and Quality (AHRQ) addressing the management of uterine fibroids included an assessment of 23 studies that examined short- and long-term outcomes following UAE. Of these, 6 studies (one RCT) compared UAE with either hysterectomy or myomectomy. These studies yielded evidence of moderate strength (consistent effects but weak design) suggesting shorter procedure times and shorter lengths of hospital stay for UAE than for hysterectomy or myomectomy. However, they provided only weak evidence (either no significant differences or inconsistent direction of effect) about the impact of UAE on complications and symptom relief. The remaining studies were case series or cohort studies, of poor or fair quality, with sample sizes ranging from 46 to 3,140. The studies did not provide consistent definitions or time points for measuring key outcomes such as complications. The largest case series on UAE reported an in-hospital complication rate of 2.7% with a .6% rate of major events and a post-discharge complication rate of 26.1% with a 4.1% rate of major events. Only one study examined rates

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of subsequent interventions for UAE and another procedure. It reported statistically significant higher rates of subsequent interventions with UAE than with myomectomy (29% vs. 3%) in follow-up ranging from 3 to 5 years. Another study reported a subsequent intervention rate of 20% at 5 years. The value of this information is limited by the lack of comparable data for other types of treatment. Laparoscopic occlusion of the uterine arteries was not addressed in the technology assessment.

There is minimal published literature regarding laparoscopic occlusion of the uterine arteries using either vascular clips or bipolar coagulation. The published literature mainly consists of case series. There is inadequate published data to permit scientific conclusions regarding these techniques.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT: 37210 Uterine fibroid embolization (UFE, embolization of the uterine arteries to treat uterine fibroids, leiomyomata), percutaneous approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the procedure

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HCPCS: No specific code(s)

ICD9: 218 Uterine leiomyoma

 218.0 Submucous leiomyoma of the uterus

 218.1 Intramural or interstitial leiomyoma of the uterus

 218.2 Subserous leiomyoma of the uterus

 218.9 Leiomyoma of the uterus, unspecified

ICD10: D25.0-D25.9 Leiomyoma of uterus (code range)

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*key article

KEY WORDS:

Embolotherapy, Laparoscopic uterine artery occlusion (LUAO), Uterine artery coagulation, Uterine artery embolization (UAE), Uterine artery occlusion, Uterine fibroid embolization (UFE).

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, neither uterine artery embolization nor laparoscopic uterine artery occlusion with bipolar coagulation or vascular clips are addressed in National or Local Medicare coverage determinations or policies.