

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

PAGE: 1 OF: 5

- *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.

| | |
|--|--|
| 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 PAGE: 2 OF: 5 |
|--|--|

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

| | |
|--|--|
| 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 PAGE: 3 OF: 5 |
|--|--|

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

Copyright © 2013 American Medical Association, Chicago, IL

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)

REFERENCES:

American Association of Gynecologic Laparoscopists (AAGL): Advancing Minimally Invasive Gynecology Worldwide. AAGL practice report: practice guidelines for the diagnosis and management of submucous leiomyomas. J Minim Invasive Gynecol 2012 Mar-Apr;19(2):152-71.

American College of Obstetricians and Gynecologists. Alternatives to hysterectomy in the management of leiomyomas. Practice Bulletin #96. Obstet Gynecol 2008 Aug;112(2):387-400; reaffirmed 2012.

*Andrews RT, et al. Patient care and uterine artery embolization for leiomyomata. J Vasc Interv Radiol 2004 Feb;15(2 Pt 1):115-20 [http://www.sirweb.org/clinical/cpg/15-115.pdf] accessed 10/9/13.

BlueCross BlueShield Association. Occlusion of uterine arteries using transcatheter embolization. Medical Policy Reference Manual Policy #4.01.11. 2013 Jul 11.

BlueCross BlueShield Association. Occlusion of uterine arteries using laparoscopic occlusion to treat uterine fibroids – archived. Medical Policy Reference Manual Policy #4.01.20. 2011 Feb 10.

*BlueCross BlueShield Association Technology Evaluation Center Assessment. Uterine artery embolization for the treatment of symptomatic uterine fibroids. 2002 Aug 17(8).

| | |
|--|--|
| 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 PAGE: 4 OF: 5 |
|--|--|

Burke CT, et al. ACR Appropriateness Criteria® on treatment of uterine leiomyomas. *J Am Coll Radiol* 2011 Apr;8(4):228-34; updated 2012 [http://www.acr.org/~/media/ACR/Documents/AppCriteria/Interventional/RadiologicManagementUterineLeiomyomas.pdf].

Goodwin SC, et al. Uterine artery embolization for treatment of leiomyomata. Long-term outcomes from the FIBROID registry. *Obstet Gynecol* 2008 Jan;111(1):22-33.

Gupta JK, et al. Uterine artery embolization for symptomatic uterine fibroids. *Cochrane Database Syst Rev*. 2012 May 16;5:CD005073.

Hehenkamp WJ, et al. Symptomatic uterine fibroids: treatment with uterine artery embolization or hysterectomy--results from the randomized clinical Embolisation versus Hysterectomy (EMMY) Trial. *Radiology* 2008 Mar;246(3):823-32.

Hirst A, et al. A multi-centre retrospective cohort study comparing the efficacy, safety and cost-effectiveness of hysterectomy and uterine artery embolisation for the treatment of symptomatic uterine fibroids. The HOPEFUL study. *Health Technol Assess* 2008 Mar;12(5):1-248, iii.

Holub Z, et al. Pregnancy outcomes after uterine artery occlusion: prospective multicentric study. *Fertil Steril* 2008 Nov;90(5):1886-91.

Homer H and Saridogan E. Uterine artery embolization for fibroids is associated with an increased risk of miscarriage. *Fertil Steril* 2010 Jun;94(1):324-30.

*Hovsepian DM, et al. Quality improvement guidelines for uterine artery embolization for symptomatic leiomyomata. *J Vasc Interv Radiol* 2004 Jun;15(6):535-41.

Jun F, et al. Uterine artery embolization versus surgery for symptomatic uterine fibroids: a randomized controlled trial and a meta-analysis of the literature. *Arch Gynecol Obstet* 2012 May;285(5):1407-13.

Kroencke TJ, et al. Acrylamido polyvinyl alcohol microspheres for uterine artery embolization: 12-month clinical and MR imaging results. *J Vasc Interv Radiol* 2008 Jan;19(1):47-57.

Manyonda IT, et al. Uterine artery embolization versus myomectomy: impact on quality of life--results of the FUME (Fibroids of the Uterus: Myomectomy versus Embolization) Trial. *Cardiovasc Intervent Radiol* 2012 Jun;35(3):530-6.

Mara M, et al. Midterm clinical and first reproductive results of a randomized controlled trial comparing uterine fibroid embolization and myomectomy. *Cardiovasc Intervent Radiol* 2008 Jan-Feb;31(1):73-85.

Marret H, et al; CNGOF (French College of Gynecology and Obstetrics). Therapeutic management of uterine fibroid tumors: updated French guidelines. *Eur J Obstet Gynecol Reprod Biol* 2012 Dec;165(2):156-64.

Martin J, et al. Complications and reinterventions in uterine artery embolization for symptomatic uterine fibroids: a literature review and meta analysis. *Cardiovasc Intervent Radiol* 2013 Apr;36(2):395-402.

Mohan PP, et al. Uterine artery embolization and its effect on fertility. *J Vasc Interv Radiol* 2013 Jul;24(7):925-30.

Pisco JM, et al. Pregnancy after uterine fibroid embolization. *Fertil Steril* 2010 Sep 24 [Epub ahead of print].

Qu X, et al. Controlled clinical trial assessing the effect of laparoscopic uterine arterial occlusion on ovarian reserve. *J Minim Invasive Gynecol* 2010 Jan-Feb;17(1):47-52.

Rashid S, et al. The effects of uterine artery embolisation and surgical treatment on ovarian function in women with uterine fibroids. *BJOG* 2010 Jul;117(8):985-9.

*Society of Obstetricians and Gynaecologists of Canada. SOGC clinical practice guidelines. Uterine fibroid embolization (UFE). Number 150, October 2004. *Int J Gynaecol Obstet* 2005 Jun;89(3):305-18 [http://sogc.org/wp-content/uploads/2013/01/150E-CPG-October2004.pdf] accessed 10/9/13.

| | |
|--|--|
| 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 PAGE: 5 OF: 5 |
|--|--|

*Spies JB, et al. Outcome of uterine embolization and hysterectomy for leiomyomas: results of a multicenter study. Am J Obstet Gynecol 2004 Jul;191(1):22-31.

Spies JB, et al. Outcomes from leiomyoma therapies: comparison with normal controls. Obstet Gynecol 2010 Sep;116(3):641-52.

Stovall DW. Alternatives to hysterectomy: focus on global endometrial ablation, uterine fibroid embolization, and magnetic resonance-guided focused ultrasound. Menopause 2011 Apr;18(4):437-44.

Toor SS, et al. Complication rates and effectiveness of uterine artery embolization in the treatment of symptomatic leiomyomas: a systematic review and meta-analysis. AJR Am J Roentgenol 2012 Nov;199(5):1153-63.

Tropeano G, et al. Non-surgical management of uterine fibroids. Hum Reprod Update 2008 May-Jun;14(3):259-74.

van der Kooij SM, et al. Uterine artery embolization vs hysterectomy in the treatment of symptomatic uterine fibroids: 5-year outcome from the randomized EMMY trial. Am J Obstet Gynecol 2010 Aug;203(2):105.e1-13.

van der Kooij SM, et al. Uterine artery embolization versus surgery in the treatment of symptomatic fibroids: a systematic review and metaanalysis. Am J Obstet Gynecol 2011 Oct;205(4):317.e1-18.

Viswanathan M, et al. Management of uterine fibroids: an update of the evidence. Evidence Report/Technology Assessment No. 154. Publication No. 07-E011. Archived. Rockville, MD: Agency for Healthcare Research and Quality. 2007 Jul [<http://archive.ahrq.gov/downloads/pub/evidence/pdf/uterupdate/uterup.pdf>] accessed 10/9/13.

*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.