



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

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Coverage Policy Number 0018

Subject **Uterine Artery Embolization**

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INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

CIGNA covers uterine artery embolization (UAE) as medically necessary for the treatment of non-pedunculated uterine leiomyomas when ALL of the following criteria are met:

- The individual is experiencing symptoms that are directly attributable to uterine fibroids (e.g., bulk pressure or pelvic pain, profuse menstrual bleeding or anemia, dyspareunia, urinary problems caused by pressure on the urethra or bladder).
- Conservative medical management has failed to control the symptoms being experienced.
- Traditional surgical evaluation deems that the individual is a candidate for UAE and hysterectomy.

CIGNA does not cover UAE in any of the following clinical situations because its use is considered experimental, investigational or unproven (this list may not be all-inclusive):

- when causes of abnormal uterine bleeding other than from a fibroid have not been sufficiently excluded
- in women with gynecologic or bladder malignancy, undiagnosed/untreated anemia, bleeding disorder, chronic pelvic inflammatory disease (PID) or other active genito-urinary infection, diabetes, vasculitis, or prior pelvic irradiation
- in women requiring surgery for associated gynecological conditions, such as pedunculated leiomyomas, other lesions, adnexal disease, uterine prolapse or stress incontinence

General Background

Uterine fibroid tumors, also referred to as leiomyomata or myomata, are the most common benign pelvic neoplasms, affecting nearly 20% of women older than 35 years of age and 40% of women older than 50 years of age (Aeby, 2008). Fibroids can lead to abnormal uterine bleeding, dysmenorrhea, and non-cyclic pelvic pain. As they increase in size, and depending on their location, fibroids can also cause constipation, urinary frequency, and infertility. The current standards of care for the treatment of symptomatic fibroids include nonsteroidal anti-inflammatory agents, oral contraceptives, pharmacological agents (e.g., gonadotropin-releasing hormone [GnRH]) for short-term therapy, myomectomy (laparoscopic or open) and hysterectomy. Intervention may be indicated under the following conditions:

- Fibroids have enlarged the uterus to a size greater than 12 weeks' gestation.
- Fibroids have grown in size by more than six weeks' gestation in six months or are causing any one of the following symptoms:
 - recurrent profuse bleeding lasting more than eight days
 - anemia from uterine blood loss
 - severe pain
 - urinary symptoms due to mass pressure in the absence of infection or other etiology, usually requiring surgical intervention

As an alternative to surgery for women with symptomatic fibroids, uterine artery embolization (UAE) was developed. First used in the 1970s as a method of managing obstetric and gynecological bleeding, UAE, also known as uterine fibroid embolization (UFE), aims to shrink or eliminate uterine fibroid tumors by interrupting the blood supply to the uterus. Prior to the development of UAE, the surgical treatment options for patients with leiomyomas (i.e., fibroids) included either hysterectomy or abdominal/laparoscopic myomectomy. Myomectomy has been the traditional treatment for women with uterine fibroids wishing to maintain fertility.

Diagnostic testing is used in the preoperative evaluation of potential candidates for UAE. Transvaginal ultrasonography (TVS) has the lowest sensitivity and specificity, but may be the best initial test based on its noninvasive nature and availability (Evans, et al., 2007). Sonohysterography utilizes an intrauterine saline contrast medium with TVS and has increased sensitivity, specificity and more discriminating positive and negative likelihood ratios for diagnosing fibroids than transvaginal ultrasound (Griffin, et al., 2005; Bradley, 2009). Magnetic resonance imaging (MRI) does have an increased sensitivity and specificity than TVS and sonohysterography and may be used when the results of testing with transvaginal ultrasonography are inconclusive. A study by Rajan et al. (2011) examined the clinical utility of ultrasound (abdominal and transvaginal) as compared to MRI for pre-procedure UAE. It was found that while localization and quantification of myomas by MRI was more accurate than ultrasound this did not alter the clinical decision to have the UAE. MRI changed the clinical management in two of 116 patients when compared to ultrasound which was not found to be significant ($p=0.5$). A study by Spielmann et al. (2006) of 49 women reviewed MRI and sonography performed before UAE found that MRI led to cancellation of uterine artery embolization in four patients. The routine use of MRI after UAE is not supported in the medical literature and is not recommended. A study by Jain et al. (2007) found a close correlation between ultrasound and MRI post UAE procedure and concluded that ultrasound alone may be used for follow-up of patients post-UAE.

UAE involves the catheterization of the uterine arteries, followed by the injection of a sclerosing agent that occludes the fibroids' essential blood supply. UAE typically is an outpatient procedure and may involve overnight care for pain control. UAE may provide a less invasive, uterus-sparing, and possibly fertility-sparing procedure for women with symptomatic uterine fibroid tumors. Reported success rates vary from 77–91% for UAE (Aeby, 2008). Reported complications from this procedure include necrosis, infection, post-embolization syndrome, and pulmonary emboli. These complications have led to emergency hysterectomies. Death due to pulmonary emboli has also been reported (Marshburn, 2006; Schirf, 2006; Vilos, 2006; Haney, 2003).

Data have shown UAE to produce a short-term reduction in fibroids, as well as short-term improvement in menstrual bleeding and other symptoms caused by fibroids. It is not known at this time if UAE is a fertility-sparing procedure. Published data on post-embolization pregnancy and live birth rates are very limited. Documented complications have included increased preterm labor, spontaneous abortion, fetal malpresentation, increased rates of cesarean sections, and postpartum hemorrhage (Marshburn, 2006; Vilos, 2006).

Literature Review

Several studies have been published that have examined the safety and efficacy of uterine embolization for treatment of uterine fibroids (Spies, et al., 2001/2005; Goodwin, et al., 2001; Razavi, et al., 2003; Mara, et al., 2005; Scheurig, et al., 2006; Edwards, et al., 2007; Dutton, et al., 2007; Mara, et al., 2008. A long-term randomized trial compared UAE to hysterectomy (Hehenkamp, et al., 2005; Volkers, et al., 2006; Volkers, et al., 2007) (EMMY trial). Five year results of this study of 177 patients noted that 23 of 81 UAE patients (28.4%) had undergone a hysterectomy because of insufficient improvement of complaints (van der Kooij, et al., 2010). Health related quality of life measures improved significantly and remained stable until the five-year follow-up, with no difference between the groups and there was a positive effect of UAE on both urinary and defecation functions. In general these studies indicate that UAE is safe and effective and control the symptoms caused by leiomyomata.

Studies have been conducted that have studied the effect of UAE on reproduction. Mara et al. (2008) reported on a randomized, controlled trial that compared UAE and myomectomy in 121 women. After a mean follow-up of 24.9 months, there were no significant differences found between the two groups in the rate of technical success, symptomatic effectiveness, postprocedural follicle stimulating hormone levels, number of reinterventions for fibroid recurrence or regrowth, or complication rates; however, it appears that myomectomy has superior reproductive outcomes in the first 2 years after treatment.

A Cochrane meta-analysis was conducted by Gupta et al. (2006) to review the benefits and/or harms from three randomized controlled trials of UAE versus other interventions for symptomatic uterine fibroids. The authors concluded that UAE offers an advantage over hysterectomy with a shorter hospital stay and a quicker return to routine activities. The authors noted that the higher minor complications rate after discharge in the UAE group as well as the unscheduled visits and readmission rates require more longer term follow-up trials to comment on its effectiveness and safety profile.

Professional Societies/Organizations

American College of Obstetricians and Gynecologists (ACOG, 2008): ACOG published an updated practice bulletin regarding alternatives to hysterectomy in the management of leiomyomas. The bulletin includes the following recommendations concerning uterine artery embolization:

- Based on long- and short-term outcomes, uterine artery embolization is a safe and effective option for appropriately selected women who wish to retain their uteri (based on Level A evidence: recommendations are based on good and consistent scientific evidence).
- The effect of uterine artery embolization on pregnancy remains understudied (based on Level C evidence: primarily consensus and expert opinion)

Cardiovascular and Interventional Radiology Society of Europe (CIRSE) and the Society of Interventional Radiology (SIR) of the United States (2004): CIRSE and SIR published its quality improvement guidelines for UAE for symptomatic leiomyomata. These guides included patient selection indications and contraindications for the use of UAE, as follows:

- Indications:
 - the presence of confirmed, symptomatic leiomyomata (e.g., ultrasound- or magnetic resonance imaging [MRI] documented presence of fibroids causing a mass effect or abnormal uterine bleeding)
 - patient education on possible complications and the possibility of amenorrhea occurring post-procedure
 - absence of active infection
 - absence of leiomyosarcoma or adnexal malignancy, unless the procedure is being performed for palliation or as an adjunct to surgery
 - absence of coagulopathy, severe contrast material allergy, and renal impairment
- Contraindications:
 - presence of immunocompromised condition
 - viable pregnancy
 - history of previous pelvic irradiation or surgery
 - chronic endometritis
 - partially treated pelvic infection
 - desire to maintain childbearing potential

- subserosal leiomyomata that is sufficiently pedunculated (attachment point < 50% of the diameter).

National Institute for Health and Clinical Excellence (NICE) (United Kingdom): NICE published guidance for UAE for fibroids (NICE, 2010). The guidance notes that, “Current evidence on uterine artery embolisation (UAE) for fibroids shows that the procedure is efficacious for symptom relief in the short and medium term for a substantial proportion of patients. There are no major safety concerns.”

Society of Obstetricians and Gynecologists of Canada (SOGC, June 2005): published evidenced-based clinical practice guidelines concerning uterine fibroid embolization (UFE). The guidelines recommend that women considering treatment of fibroids should be counseled that, while the early results of uterine artery embolization are encouraging, no long-term data exist. UFE should only be considered for women with symptomatic or problematic fibroids who might otherwise be advised to have surgical treatment. UFE as a treatment for fibroids in patients wishing to preserve their fertility should be undertaken with full disclosure to the patient about the limitations of such a procedure and the lack of existing data regarding future fertility and pregnancy outcomes.

Summary

While a limited number of large population, well-designed clinical trials evaluating the effectiveness of UAE on menorrhagia and fibroids have been published in the peer-reviewed scientific literature, there is sufficient evidence to support the safety and effectiveness of uterine artery embolization (UAE) for the treatment of uterine fibroids in a specific subset of individuals. Additional prospective studies are needed to determine the effect that this procedure has on ovarian function, fertility and a woman’s ability to carry a fetus to term after uterine fibroid embolization. Additional studies are also needed to determine if there is an upper limit to the size or number of fibroids that can be safely treated using this technique, as these could be predictive indicators of the response to UAE.

Coding/Billing Information

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

Covered when medically necessary:

CPT®* Codes	Description
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

ICD-9-CM Diagnosis Codes	Description
218.0 – 218.9	Uterine leiomyoma

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
195.3	Malignant neoplasm of pelvis
233.9	Carcinoma in situ of other and unspecified urinary organs
614.1	Chronic salpingitis and oophoritis
614.9	Unspecified inflammatory disease of female pelvic organs and tissues
618.1	Uterine prolapse without mention of vaginal wall prolapse
625.3	Dysmenorrhea

625.6	Stress incontinence, female
626.8	Disorders of menstruation and other abnormal bleeding from female genital tract; Other
626.9	Disorders of menstruation and other abnormal bleeding from female genital tract; Unspecified

***Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.**

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	1/15/2008	0018	Uterine Artery Embolization
Great-West Healthcare	8/29/2006	01.247.03	Uterine Artery Embolization of Fibroids

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