

4.01.11	<b>Occlusion of Uterine Arteries Using Transcatheter Embolization</b>	
Section 4.0 OB/Gyn/Reproduction	Effective Date September 30, 2014	
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### Description

Uterine leiomyomata, also called fibroids or myomas, are common benign muscle tumors of the uterus. They can be located within the uterine cavity (submucosal myomas), within the wall of the uterus (intramural myomas), or on the external surface of the uterus (subserosal myomas).

Transcatheter uterine artery embolization (UAE) is a minimally invasive technique that involves the injection of small particles into the uterine arteries to block the blood supply to the uterus and uterine fibroids. It potentially serves as an alternative to hysterectomy.

Laparoscopic bipolar coagulation of uterine arteries has been investigated as an alternative to UAE. This technique involves laparoscopic ligation of uterine arteries by means of coagulation using bipolar current.

### Related Policies

- Presacral Neurectomy (PSN) and Laparoscopic Uterine Nerve Ablation (LUNA)
- MRI-Guided Focused Ultrasound for the Treatment of Uterine Fibroids

### Policy

Transcatheter embolization of uterine arteries as a treatment of uterine fibroids or as a treatment of postpartum uterine hemorrhage may be considered **medically necessary**.

One repeat transcatheter embolization of uterine arteries to treat persistent symptoms of uterine fibroids after an initial uterine artery embolization may be considered **medically necessary** (See Policy Guidelines).

Transcatheter embolization for the management of all other indications, including cervical ectopic pregnancy and uterine arteriovenous malformation is considered **investigational**.

### Policy Guidelines

#### Patient Selection Criteria

*Initial procedure*

There are no specific criteria for uterine artery embolization regarding the size, location, or multiplicity of fibroid tumors. The American College of Obstetricians and Gynecologists (ACOG) has suggested the following general criteria for treatment of fibroid tumors:

- Asymptomatic fibroids of such size that they are palpable abdominally and are a concern to the patient;
- Excessive uterine bleeding as evidenced by either profuse bleeding lasting more than 8 days, or anemia due to acute or chronic blood loss;
- Pelvic discomfort caused by myomata, either acute severe pain, chronic lower abdominal pain, or low back pressure or bladder pressure with urinary frequency not due to urinary tract infection.

#### Repeat procedure

One repeat UAE may be performed when there is documentation of continued symptoms such as bleeding or pain. Repeat procedures may be most appropriate when there are persistent symptoms in combination with findings on imaging of an incomplete initial procedure, as evidenced by continued blood flow to the treated regions. Limited data from case series suggest a high rate of success following repeat procedures for this purpose, with the majority of patients reporting relief of symptoms.

#### Coding Issues

Effective in 2014, there is a nonspecific embolization code for this procedure:

- 37243: Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction.

Between 2007 and 2014, there was a specific CPT code for this procedure:

- 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.

#### Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## Rationale

### Background

Uterine leiomyomata (i.e., fibroids) are extremely common benign tumors that can be located primarily within the uterine cavity (submucosal fibroids) or on the serosal surface of the uterus. Treatment for uterine fibroids is usually sought when they are associated with menorrhagia, pelvic pain, urinary symptoms (i.e., frequency), or are suspected to be the cause of infertility. Treatment options include medical therapy with gonadotropin agonists or gestagen suppression or various types of surgical therapy. Hysterectomy is considered the definitive surgical treatment for those who no longer wish to maintain fertility. Various types of myomectomy, which describes removal of the fibroid with retention of the uterus, have also been described. Hysteroscopic myomectomy involves removal of submucosal fibroids using either a resectoscope or a laser. Subserosal fibroids can be removed via an open abdominal or laparoscopic approach. Laparoscopic laser coagulation of uterine fibroids is a unique approach in that the fibroid is not physically removed, but instead multiple (up to 75) laparoscopic laser punctures of the uterine fibroids are performed in an effort to devascularize the fibroid and induce atrophy.

There is interest in techniques to directly devascularize the uterine fibroid by interrupting the uterine arteries. One technique, UAE involves selective catheterization of the uterine arteries with injection of embolization material. UAE has also been used to control bleeding in other situations such as severe postpartum hemorrhage, treatment of cervical ectopic pregnancy, and treatment of bleeding uterine arteriovenous malformation.

### Regulatory Status

In April 2000, Embosphere® Microspheres (Biosphere Medical) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for hypervascularized tumors and arteriovenous malformations. In November 2002, this product was cleared for marketing specifically for use in uterine fibroid embolization. Since that time, several other devices have been cleared for marketing. In 2003, Contour® Emboli PVA (Boston Scientific) was cleared for the embolization of peripheral hypervascular tumors and peripheral arteriovenous malformations. In March 2004, the Contour SE™ (Boston Scientific) was cleared by FDA for treatment of uterine fibroids. In December 2008, Cook Incorporated Polyvinyl Alcohol Foam Embolization Particles received FDA marketing clearance for use in uterine fibroid embolization.

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Between 2007 and 2014, there was a specific CPT code for this procedure:

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.

## Literature Review

### UAE for treatment of uterine fibroids

#### Initial UAE procedure

A number of randomized controlled trials (RCTs) evaluating UAE for treatment of uterine fibroids have been published. In addition, there have been several systematic reviews of these RCTs. A 2012 Cochrane review included 5 RCTs comparing UAE to surgery in women with symptomatic uterine fibroids.(2) Pooled analyses did not find statistically significant differences in patient satisfaction with UAE or surgery after 2 years (5 trials; odds ratio [OR], 0.69; 95% confidence interval [CI], 0.40 to 1.21) or 5 years (2 trials; OR=0.90; 95% CI, 0.45 to 1.90). UAE was associated with a lower procedure length, shorter hospital stay, shorter time to resumption of routine activities, and lower likelihood of blood transfusion. There were no significant differences between UAE and surgery in terms of major complications, but there was a higher rate of minor complications and reintervention with UAE.

In 2011, van der Kooij et al published a meta-analysis of RCTs comparing UAE and surgery for treating symptomatic uterine fibroids and presented up to 5-year follow-up data.(3) The investigators identified 11 articles reporting on 5 RCTs. The overall intraprocedural and early postprocedural complication rates were similar with the 2 procedures. However, length of hospital stay, need for blood transfusion, and febrile morbidity were significantly lower in the UAE group compared with the surgery group. At 12 months, a pooled analysis of 2 studies found a significantly higher reintervention rate in the UAE group compared with the surgery group (OR=5.78; 95% CI, 2.14 to 15.58). Pooled analyses of quality-of-life variables at 12 months did not find significant differences between groups. Results were similar after 5 years. The reintervention rate was significantly higher at 5 years, according to a pooled analysis of 2 trials (OR=5.41; 95% CI, 2.48 to 11.81).

A 2013 systematic review by Martin et al focused on complication and reintervention rates following UAE for symptomatic uterine fibroids.(4) Eight RCTs comparing UAE with another intervention were included. Among the 350 UAE cases in the RCTs, the most common complications were discharge and fever (4%), postembolization syndrome (2.9%), pain (2.9%), and groin complications (2.9%). Six trials also provided data on 346 cases of surgery for uterine fibroids. The most common complications following surgery were urinary stress incontinence (3.8%), pressure symptoms (2.9%), and menorrhagia (2.6%). Three trials presented reintervention data and, in a meta-analysis of these studies, there was a significantly higher risk of reintervention after UAE compared with surgery, but a wide CI indicating imprecision of the risk estimate (OR=6.04; 95% CI, 2.0 to 18.1).

Representative trials are described next.

The Randomized Trial of Embolization versus Surgical Treatment for Fibroids (REST) multicenter trial assigned patients in a 2:1 ratio to undergo UAE (n=106) or surgery (43 hysterectomies and 8 myomectomies).(5) The embolization group had lower postoperative pain (3.0 vs 4.6, respectively) and faster recovery (e.g., 1- vs 5-day median hospitalization, respectively). Of 7 identified pregnancies in the UAE group, 2 resulted in successful live births. Five-year follow-up data from the REST trial were published in 2011.(6) A total of 144 of 157 (92%) randomized patients were included in the 5-year analysis. Quality-of-life and symptom scores were similar in the 2 groups at 5 years. For example, the mean symptom score was 4.5 in the UAE group and 4.8 in the surgery group (scores ranged from 15 [markedly worse] to 5 [markedly better]). By the 5-year follow-up, 27 of 106 (25%) in the UAE group and 2 of 51 (4%) in the surgery group had received an additional intervention for continued or recurrent symptoms. The total rate

of further intervention for symptoms or adverse events over the 5-year period was 32% in the UAE group and 4% after surgery. In the UAE group, there were 3 technical failures of the procedure, 8 repeat UAEs, and 18 hysterectomies. Note that 1 woman had both a repeat UAE and a hysterectomy, and 2 women were not embolized after randomization and subsequently underwent surgery.

The Embolization versus hysterectomy (EMMY) trial from the Netherlands included 177 women with uterine fibroids and heavy menstrual bleeding who were scheduled to undergo hysterectomy. They were randomized to receive UAE (n=88) or hysterectomy (n=89).<sup>(7,8)</sup> By the 2-year follow-up, 19 of the 81 (23%) women who actually received UAE had undergone a hysterectomy. An analysis of health-related quality-of-life outcomes at 2 years found similar improvement in both groups overall. The Defecation Distress Inventory (DDI) score improved significantly in only the UAE group starting at 6 months. A report of 5-year outcome data from the EMMY trial was published in 2010.<sup>(9)</sup> A total of 70 of the 89 (79%) patients originally randomized to the hysterectomy group and 75 of 88 (85%) in the UAE group completed questionnaires at 60 months. In an intention-to-treat analysis, 23 of 81 (28.4%) women who had received UAE underwent hysterectomy during the 5 years. Including the hysterectomies, 58 of 81 (71.6%) women in the UAE group no longer had menorrhagia. There were no significant differences between groups in health-related quality of life at 5 years, as assessed by mental and physical components of the 36-Item Short-Form Health Survey (SF-36). For example, the mean difference in change scores at 60 months on the physical component summary of the SF-36 was 1.26 (95% CI, 2.16 to 4.70). Within the hysterectomy group, there was a statistically significantly worse physical health score at 5 years (mean, 6.87) compared with 2 years (mean, 7.26; p=0.01). The UAE group did not have a significant change in the mean physical health score, which was 6.87 at 5 years and 5.80 at 2 years (p=0.34). There was also not a statistically significant difference in the rate of reported urinary incontinence. Similar to the 2-year finding, the DDI significantly improved over time in the UAE group but not in the group assigned to initial hysterectomy. There was not, however, a statistically significant difference between groups in defecation function at 5 years. The authors did not discuss their level of statistical power to detect between-group differences.

In 2012, findings of the Fibroids of the Uterus: Myomectomy versus Embolization (FUME) trial from the U.K. were published.<sup>(10)</sup> The investigators randomized women with symptomatic fibroids to UAE (n=82) or myomectomy (n=81). Mean hospital stay was significantly shorter after UAE than surgery (2 vs 4 days, respectively; p<0.001). There were no significant differences in minor or major complications. A total of 120 of 163 (74%) were available for the analysis of quality of life, the primary outcome measure. There were no significant differences between groups in change in quality-of-life scores from baseline to 1 year. Nine patients (11%) in the UAE group required additional intervention, and 3 patients (4%) in the myomectomy group later underwent hysterectomy.

An RCT by Hald et al in Norway evaluated clinical outcomes in 66 premenopausal women (mean age, 43 years) with symptomatic uterine fibroids who were randomized to treatment with either laparoscopic occlusion of uterine arteries or UAE.<sup>(11)</sup> Women who wanted to bear children in the future, had a large uterus, had undergone multiple previous open abdominal surgeries, and who had bleeding disorders were excluded. The primary outcome was reduction in blood loss at 6 months' postintervention, as measured by a pictorial blood loss assessment chart. Fifty-eight women underwent treatment, 29 with UAE and 29 with laparoscopic occlusion. The proportion of women who had a reduction in blood loss after 6 months did not differ between the treatment groups (52% after UAE and 53% after laparoscopy, respectively; p=0.96). An additional publication reported on follow-up data at a median of 48 months after treatment (range, 8-73

months).(12) The cumulative clinical failure and recurrence rate was significantly lower for patients in the UAE group (17%, n=5) compared with the laparoscopy group (48%, n=17; p=0.02). Moreover, fewer patients in the UAE group (7%, n=2) had a hysterectomy than in the laparoscopy group (28%, n=8; p=0.41). The authors concluded that UAE is superior to laparoscopic occlusion of uterine arteries for treatment of uterine fibroids.

### Section Summary

There is evidence from RCTs that the net health outcome after UAE for uterine fibroids is reasonable compared with surgery. Meta-analyses of RCTs have found similar levels of quality of life after 5 years among women receiving UAE or surgery, although there were more reinterventions in the UAE group.

#### Repeat UAE to treat recurrent or persistent symptoms

No RCTs focusing on repeat UAE were identified; there are published case series. In 2009, McLucas et al published a study in which the charts of 1058 women who had undergone initial bilateral UAE at several U.S. centers were reviewed.(13) Forty-two (4%) patients had documentation of persistent symptoms, and they were offered a second bilateral UAE. Thirty-nine patients had repeat procedures, and 34 of these (87%) completed a follow-up questionnaire at least 6 months postembolization. Before the second UAE procedure, 27 of the 34 (79%) women reported severe bleeding, and only 2 (6%) women reported severe bleeding after the procedure. Similarly, the number of women with severe pain decreased from 20 (59%) to 2 (6%), and with severe pressure decreased from 18 (53%) to 2 (6%). A total of 4 women experienced severe levels of 1 or more symptoms after the second UAE. Prospective comparative studies are needed to confirm the findings.

In 2006, Yousefi et al reported on 24 patients who underwent repeat embolization for recurrent or persistent symptoms 6 to 66 months after the initial procedure.(14) The most common symptoms were pressure and/or bulk symptoms (n=15), recurrent heavy bleeding (n=12), and pelvic pain or cramping (n=7). Follow-up data were available on 21 of 24 (87.5%) after the second UAE; 19 (90%) reported symptom control.

### Section Summary

There is a lack of RCTs on repeat UAE for treatment of symptoms associated with uterine fibroids. However, there are data from case series showing a high rate of success after a second UAE for recurrent or persistent symptoms.

#### Comparison of products used in UAE

A 2013 meta-analysis by Das et al identified 10 studies comparing the efficacy of 1 embolic agent used in UAE to another intervention or comparing 2 embolic agents with one another.(15) Five of the studies were RCTs and 5 were nonrandomized controlled trials. Embosphere microspheres were used in all of the RCTs. In a pooled analysis of data from 2 studies comparing Embosphere to spherical polyvinyl alcohol (PVA) for treatment of uterine fibroids, there was not a statistically significantly between-group difference in outcomes (uterine volume reduction and dominant fibroid volume reduction). Data from other studies were not pooled, but a qualitative analysis of study findings did not suggest that any agent was clearly superior or inferior to any other agent.

As a recent example, a 2014 RCT by Shlansky-Goldberg et al randomized 60 women with symptomatic uterine fibroids to UAE using either Embosphere microspheres (n=30) or spherical PVA (n=30). The study was funded by the manufacturer of the spherical PVA product. The primary study outcome was complete or near-complete infarction of the dominant tumor (an infarction rate of at least 91%), as measured by magnetic resonance imaging 24 hours after UAE. The primary end point was achieved in 29 of 29

(100%) cases in the spherical PVA group and 28 of 30 (93%) cases in the Embosphere group; the difference between groups was not statistically significant. One patient was excluded from the analysis. Similarly, at 3 months, there was not a statistically significant difference in the rate of complete or near-complete infarction rates between groups.

### Section Summary

The available evidence from multiple RCTs does not suggest that any embolization agent is clearly superior to any other agent.

#### **UAE for treatment of postpartum uterine hemorrhage**

No RCTs or other comparative studies evaluating UAE for treating postpartum hemorrhage were identified. In 2012, Rath et al published a systematic review of literature on second-line treatment of this condition.(16) The authors stated that there is a lack of RCTs on arterial embolization for postpartum hemorrhage and the emergent and multifactorial nature of this condition, as well as potential ethical issues, makes it difficult to conduct a randomized trial. The review summarized the success rate of arterial embolization for postpartum hemorrhage reported in case series as ranging from 70% to 100%, and from 60% to 83% in placenta accreta. The authors noted that UAE should not be performed in patients with excessive bleeding or when the patient is hemodynamically unstable.

Representative larger case series are described next.

In 2013, Kim et al evaluated data on 60 women who underwent UAE for treatment of postpartum hemorrhage at a single center in Korea.(17) The clinical success rate (which was not explicitly defined) was reported as 96%. Eleven patients treated with UAE experienced transient fever after the procedure, and there was 1 case of ovarian failure. During the time of data collection for this study, another 61 patients at the same center underwent cesarean hysterectomy for treatment of postpartum hemorrhage; the success rate associated with that procedure was 93%.

In 2011, Ganguli et al published data on 66 women who underwent UAE for the treatment of postpartum hemorrhage.(18) The clinical success rate, defined as obviation of hysterectomy, was 95%. Three of 66 (5%) women had a subsequent hysterectomy. In addition to the 3 clinical failures, there were 3 (5%) major complications after UAE: 1 case of lower-extremity deep vein thrombosis, 1 case of postprocedural pancreatitis, and 1 admission for intravenous antibiotic treatment for presumed endometritis. Nine pregnancies after UAE were identified; there were 2 spontaneous abortions and 7 viable gestations.

In 2009, Kirby et al published a retrospective analysis of data from 43 women who underwent UAE for primary postpartum hemorrhage.(19) In this study, clinical success was defined as cessation of bleeding without need for repeat embolization, laparotomy or hysterectomy and without mortality. Eight of 43 (19%) of women had a hysterectomy before UAE. Of the remaining 35 women, clinical success was achieved in 29 women (83%). Considering the sample as a whole, the clinical success rate was 29 of 43 (67%). Complications among women who had a UAE without a previous hysterectomy included 1 case of a groin hematoma, 1 inadvertent perforation of the left obturator artery during UAE, 1 bleeding necrotic fibroid tumor, and 1 case of symptoms consistent with endometritis.

### Section Summary

There is a lack of RCTs on repeat UAE for treatment of postpartum hemorrhage. Conducting RCTs may be particularly difficult in this emergent and clinically complex situation. Data from case series have shown a high rate of success after UAE for postpartum hemorrhage.

### UAE for treatment of cervical ectopic pregnancy

No RCTs or other comparative studies evaluating UAE for treating cervical ectopic pregnancy were identified. The published literature consisted of case series with small numbers of patients. Sample sizes ranged from 2 to 20 patients, and most studies had fewer than 10 patients. The largest prospective series was conducted in China by Xiaolin et al.(20) Patients underwent UAE and in conjunction with methotrexate injections before, during, and after the UAE procedure. Median follow-up was 12 months (range, 1-50 months). Two of 20 patients (10%) had recurrent vaginal bleeding; the other 18 had no significant bleeding after UAE. Five patients (25%) had an additional curettage procedure due to bleeding and/or high levels of beta (b)-hCG. The uterus was preserved in all patients, and normal menses resumed after 2 to 4 months. Eight of 16 (50%) women who attempted another pregnancy achieved a normal pregnancy within 1 year. There were 2 miscarriages and 6 live births at term.

### Section Summary

There is a lack of RCTs in UAE for treating cervical ectopic pregnancy and only a few small case series were available.

### UAE for treatment of bleeding uterine arteriovenous malformation

No RCTs or other comparative studies evaluating UAE for treating uterine arteriovenous malformation were identified. The published literature consists of case reports and a small case series. The series, published in 2014 by Kim et al in Korea, retrospectively reviewed data from a single center on 19 patients who underwent UAE as first-line treatment of bleeding uterine arteriovenous malformation.(21) All patients presented with intermittent or progressive vaginal bleeding after gynecologic procedures or obstetric events. The UAE procedures were bilateral, and a variety of embolization agents were used. A total of 17 of 19 patients (89.5%) had immediate clinical success following the UAE. Clinical success was defined as cessation of bleeding without symptom recurrence and resolution of the uterine arteriovenous malformation on postoperative imaging studies.

### Section Summary

The available limited noncomparative evidence is insufficient to determine the effect of UAE on health outcomes in patients with bleeding uterine arteriovenous malformation.

### Impact of UAE treatment on fertility and pregnancy outcomes

Several systematic reviews have been published. In 2014, Doumouchtis et al identified 17 studies with a total of 675 participants reporting on fertility outcomes after UAE for postpartum hemorrhage.(22) To be included in the review, studies needed to report on a minimum of 5 cases. None of the studies identified were RCTs. A total of 168 of the 675 patients (25%) wanted a pregnancy following UAE, and 126 of the 168 (75%) women who desired pregnancy achieved conception. There were a total of 136 term live births and 30 cases of pregnancy loss (ectopic pregnancy, miscarriage, elective abortion).

Previously, in 2013, Mohan et al identified 21 studies reporting pregnancy outcomes and/or pregnancy complications after UAE for treatment of either postpartum hemorrhage or uterine fibroids.(23) The authors reported that the cumulative pregnancy and miscarriage rates among women trying to conceive following UAE for uterine fibroids

was 59% and 28%, respectively, and the cumulative live birth rate was 65%. The term delivery rate was 61%. In the studies on UAE for postpartum hemorrhage, the cumulative pregnancy rate, based on a small number of pregnancies, was 87.2%. Rates of miscarriage and live births were not reported following UAE for postpartum hemorrhage. Most of the studies included in the systematic review were observational and had no or inadequate controls. There was only 1 RCT. This study, by Mara et al in Czech Republic, randomized 121 women with uterine fibroids who desired future pregnancies to UAE or myomectomy.(24) Participants were followed-up for a mean of 25 months; they were advised to wait for at least 6 months after the procedure before they attempted pregnancy. At final follow-up, 13 of 26 women (50%) in the UAE group who tried to conceive became pregnant compared with 31 of 40 (76%) in the myomectomy group; the difference between groups was not statistically significant. Among women in the UAE group who became pregnant, the abortion rate was 64% and the delivery rate was 19%. In the myomectomy group, the abortion rate was 23%, and the delivery rate was 48%.

### **Section Summary**

Reviews of fertility and pregnancy outcomes after UAE suggest that successful pregnancy is possible after UAE for treatment of uterine fibroids or postpartum hemorrhage. One review found higher rates of miscarriage and postpartum hemorrhage after UAE for treatment of uterine fibroids compared with treatment of fibroids with myomectomy. There are limited data on pregnancy outcomes in women who became pregnant following UAE for treatment of postpartum hemorrhage.

### **Ongoing Clinical Trials**

[The FIRSST: Comparing MRgFUS \(MR guided Focused Ultrasound\) versus UAE \(Uterine Artery Embolization\) \(NCT00995878\)](#)(25): This is an RCT comparing MRgFUS with UAE in premenopausal women at least 25 years of age who have symptomatic uterine fibroids. The primary outcome is reduction in symptoms, including pain, as assessed by validated instruments. The expected enrollment is 180 participants and the expected date of study completion is December 2015.

[Uterine Artery Embolization \(UAE\) Versus High-Intensity-Focused-Ultrasound \(HIFU\) for Treatment of Uterine Fibroids \(NCT01834703\)](#)(26): This RCT is testing the safety and efficacy of HIFU compared with UAE in women aged 30 to 47 with uterine fibroids. The primary outcome is the treatment success rate after 6 months. The investigators plan to enroll 200 women and the estimated study completion date is May 2014.

### **Summary**

Uterine artery embolization (UAE) involves selective catheterization of the uterine arteries with injection of embolization material. The available evidence suggests that the net health outcome after UAE for uterine fibroids is reasonable compared with surgery. Although there are a lack of controlled studies on repeat UAE, case series have found a high rate of success after a second UAE for recurrent or persistent symptoms. Thus, UAE for initial treatment of uterine fibroids and 1 repeat UAE to treat persistent symptoms may be considered medically necessary. Evidence does not suggest that any embolization agent used to treat uterine fibroids is superior to any other agent.

There are no controlled studies evaluating UAE for other indications, including postpartum hemorrhage, cervical ectopic pregnancy, and uterine arteriovenous malformation. However, due to available evidence from case series and strong support from clinical reviewers, UAE for postpartum hemorrhage may be considered medically necessary. In the absence of either controlled studies or strong clinical support, UAE for additional indications is considered investigational.

### Practice Guidelines and Position Statements

In 2004, the American College of Obstetricians and Gynecologists (ACOG) issued a committee opinion on UAE.(27) The statement offered the following conclusions: “.... There is insufficient evidence in the current literature to ensure safety in women desiring to retain their fertility. Furthermore, pregnancy-related outcomes remain understudied. Therefore, the procedure should be considered investigational or relatively contraindicated in women wishing to retain fertility. The use of uterine artery embolization in postmenopausal women is rarely, if ever, indicated.” In 2012, ACOG reaffirmed a 2008 Practice Bulletin titled “Alternatives to Hysterectomy in the Management of Leiomyomas.”(28) This Bulletin contained the following statement regarding UAE: “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.”

The 2010 (reviewed and unchanged in 2012), Quality Improvement Guidelines from the Society of Interventional Radiology stated that uterine artery embolization is indicated in women with uterine leiomyomas that are causing significant symptoms.(29) Absolute contraindications to UAE are viable pregnancy, active infection, and suspected uterine, cervical, or adnexal malignancy (unless the procedure is being performed for palliation or in conjunction with surgery). A desire to maintain fertility is a relative contraindication.

In 2013 ACOG reaffirmed a 2008 Practice Bulletin (No. 76) on management of postpartum hemorrhage.(28) The bulletin states that UAE may be indicated under the following circumstances:

A patient with stable vital signs and persistent bleeding, especially if the rate of loss is not excessive, may be a candidate for arterial embolization. Radiographic identification of bleeding vessels allows embolization with Gelfoam, coils, or glue. Balloon occlusion is also a technique used in such circumstances. Embolization can be used for bleeding that continues after hysterectomy or can be used as an alternative to hysterectomy to preserve fertility.

### References

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Uterine artery embolization for treatment of symptomatic uterine fibroids. TEC Assessments 2002; Volume 17, Tab 8.
2. Gupta JK, Sinha A, Lumsden MA et al. Uterine artery embolization for symptomatic uterine fibroids. Cochrane Database Syst Rev 2012; 5:CD005073.
3. Van dKSM, Bipat S, Hehenkamp WJ et al. Uterine artery embolization versus surgery in the treatment of symptomatic fibroids: a systematic review and meta-analysis. Am J Obstet Gynecol 2011; 205(4):317.e1-8.
4. Martin J, Bhanot K, Athreya S. Complications and reinterventions in uterine artery embolization for symptomatic uterine fibroids: a literature review and meta analysis. Cardiovasc Intervent Radiol 2013; 36(2):395-402.
5. Edwards RD, Moss JG, Lumsden MACotRToEvSTfF et al. Uterine-artery embolization versus surgery for symptomatic uterine fibroids. N Engl J Med 2007; 356(4):360-70.
6. Moss JG, Cooper CG, Khaund A et al. Randomised comparison of uterine artery embolization (UAE) with surgical treatment in patients with symptomatic uterine fibroids (REST trial): 5-year results. BJOG 2011; 118(8):936-44.
7. Hehenkamp WJ, Volkers NA, Donderwinkel FJ et al. Uterine artery embolization versus hysterectomy in the treatment of symptomatic uterine fibroids (EMMY trial): peri- and postprocedural results from a randomized controlled trial. Am J Obstet Gynecol 2005; 193(5):1618-29.

8. Volkers NA, Hehenkamp WJ, Birnie E et al. Uterine artery embolization versus hysterectomy in the treatment of symptomatic uterine fibroids: 2 years' outcome from the randomized EMMY trial. *Am J Obstet Gynecol* 2007; 196(6):519.
9. van dKSM, Hehenkamp WJ, Volkers NA 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; 203(2):105.e1-13.
10. Manyonda IT, Bratby M, Horst JS et al. Uterine artery embolization versus myomectomy: Impact on quality of life-results from the FUME (Fibroids of the Uterus: Myomectomy versus Embolization) trial. *Cardiovasc Intervent Radiol* 2012; 35(3):530-6.
11. Hald K, Klow NE, Qvigstad E et al. Laparoscopic occlusion compared with embolization of uterine vessels: a randomized controlled trial. *Obstet Gynecol* 2007; 109(1):20-7.
12. Hald K, Noreng HJ, Istre O et al. Uterine artery embolization versus laparoscopic occlusion of uterine arteries for leiomyomas: long-term results of a randomized comparative trial. *J Vasc Interv Radiol* 2009; 20(10-Jan):1303-10.
13. McLucas B, Reed RA. Repeat uterine artery embolization following poor results. *Minim Invasive Ther Allied Technol* 2009; 18(2):82-6.
14. Yousefi S, Czeyda-Pommersheim F, White AM et al. Repeat uterine artery embolization: indications and technical findings. *J Vasc Interv Radiol* 2006; 17(12):1923-9.
15. Das R, Champaneria R, Daniels JP et al. Comparison of Embolic Agents Used in Uterine Artery Embolization: A Systematic Review and Meta-Analysis. *Cardiovasc Intervent Radiol* 2013.
16. Rath W, Hackethal A, Bohlmann MK. Second-line treatment of postpartum haemorrhage (PPH). *Arch Gynecol Obstet* 2012; 286(3):549-61.
17. Kim TH, Lee HH, Kim JM et al. Uterine artery embolization for primary postpartum hemorrhage. *Iran J Reprod Med* 2013; 11(6):511-8.
18. Ganguli S, Stecker MS, Pyne D et al. Uterine artery embolization in the treatment of postpartum uterine hemorrhage. *J Vasc Interv Radiol* 2011; 22(2):169-76.
19. Kirby JM, Kachura JR, Rajan DK et al. Arterial embolization for primary postpartum hemorrhage. *J Vasc Interv Radiol* 2009; 20(8):1036-45.
20. Xiaolin Z, Ling L, Chengxin Y et al. Transcatheter intraarterial methotrexate infusion combined with selective uterine artery embolization as a treatment option for cervical pregnancy. *J Vasc Interv Radiol* 2010; 21(6):836-41.
21. Kim T, Shin JH, Kim J et al. Management of bleeding uterine arteriovenous malformation with bilateral uterine artery embolization. *Yonsei Med J* 2014; 55(2):367-73.
22. Doumouchtsis SK, Nikolopoulos K, Talaulikar V et al. Menstrual and fertility outcomes following the surgical management of postpartum haemorrhage: a systematic review. *BJOG* 2014; 121(4):382-8.
23. Mohan PP, Hamblin MH, Vogelzang RL. Uterine Artery Embolization and Its Effect on Fertility. *J Vasc Interv Radiol* 2013.
24. Mara M, Maskova J, Fucikova Z et al. Midterm clinical and first reproductive results of a randomized controlled trial comparing uterine fibroid embolization and myomectomy. *Cardiovasc Intervent Radiol* 2008; 31(1):73-85.
25. Sponsored by the Mayo Clinic. The FIRSST: Comparing MRgFUS (MR guided Focused Ultrasound) versus UAE (Uterine Artery Embolization) (NCT00995878). Available online at: [clinicaltrials.gov](https://clinicaltrials.gov). Last accessed May, 2014.
26. Sponsored by the Chinese University of Hong Kong. Uterine Artery Embolization (UAE) Versus High-Intensity-Focused-Ultrasound (HIFU) for Treatment of Uterine

Fibroids (NCT01834703). Available online at: [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Last accessed May, 2014.

- 27. American College of Obstetricians and Gynecologists (ACOG). Committee Opinion No. 293: Uterine artery embolization. *Obstet Gynecol* 2004; 103(2):403-4.
- 28. American College of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin: Alternatives to hysterectomy in the management of leiomyomas. *Obstet Gynecol* 2008; 112(2 pt 1):387-400.
- 29. Stokes LS, Wallace MJ, Godwin RB et al. Quality improvement guidelines for uterine artery embolization for symptomatic leiomyomas. *J Vasc Interv Radiol* 2010; 21(8):1153-63.
- 30. Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 4.01.11 (July 2014).

### Documentation Required for Clinical Review

- History and physical and/or consultation reports including:
  - Past medical/surgical treatment and response
  - Reason for treatment request
  - Treatment plan

### Post Service

- Operative report

### Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.*

### MN/IE

The following service/procedure may be considered medically necessary in certain instances and investigational in others. Services may be medically necessary when policy criteria are met. Services are considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

Type	Code	Description
CPT®	37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
	37204	Transcatheter occlusion or embolization (e.g., for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any

		method, non-central nervous system, non-head or neck
	36245-36247	Selective catheter placement, arterial system; each first, second, or third order branch, respectively
HCPCS	None	
ICD-9 Procedure	68.25	Uterine artery embolization [UAE] without coils
ICD-10 Procedure	<b>For dates of service on or after 10/01/2015</b>	
	04LE3DT, 04LE3ZT, 04LF3DU, 04LF3ZU	Surgical, lower arteries, occlusion, internal iliac artery, percutaneous, uterine artery (code by left or right, and intraluminal or no device)
ICD-9 Diagnosis	All Diagnoses	
ICD-10 Diagnosis	<b>For dates of service on or after 10/01/2015</b>	
	All Diagnoses	

### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
2/25/1998	New Policy Adoption	Medical Policy Committee
2/23/2000	Policy Review	Medical Policy Committee
5/30/2000	Policy revision with position change	Medical Policy Committee
8/1/2002	Coding update	Administrative Review
11/2/2002	Coding update	Administrative Review
4/2/2010	Policy Revision with title change from Uterine Artery Embolization (UAE) for Uterine Myomata (Fibroids)	Medical Policy Committee
1/11/2013	Policy revision with position change	Medical Policy Committee
4/4/2014	Coding Update	Administrative Review
9/30/2014	Policy revision with position change Policy title change from Uterine Artery Embolization	Medical Policy Committee

### Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

#### Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

*The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.*