



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

## Occlusion of Uterine Arteries Using Transcatheter Embolization or Laparoscopic Occlusion to Treat Uterine Fibroids

Policy # 00130

Original Effective Date: 03/25/2002

Current Effective Date: 11/20/2013

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

#### *Initial Procedure*

Based on review of available data, the Company may consider transcatheter embolization of uterine arteries as a treatment of uterine fibroids or as a treatment of postpartum uterine hemorrhage to be **eligible for coverage**.

#### Patient Selection Criteria

The use of transcatheter embolization of uterine arteries as a treatment of uterine fibroids or as a treatment of postpartum uterine hemorrhage may be considered for coverage when ONE of the following criteria is met:

- Asymptomatic fibroid of such size that they are palpable abdominally and are a concern to the patient; OR
- Excessive uterine bleeding as evidenced by either profuse bleeding lasting more than eight days, or anemia due to acute or chronic blood loss; OR
- 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*

Based on review of available data, the Company may consider one repeat transcatheter embolization of uterine arteries to treat persistent symptoms of uterine fibroids after an initial uterine artery embolization (UAE) to be **eligible for coverage**.

*Note: One repeat uterine artery embolization (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.*



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## **When Services Are Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers the use of transcatheter embolization of uterine arteries as a treatment of uterine fibroids when patient selection criteria are not met to be **investigational\***.

Based on review of available data, the Company considers transcatheter embolization for the management of cervical ectopic pregnancy to be **investigational\***.

Based on review of available data, the Company considers laparoscopic occlusion of the uterine arteries using bipolar coagulation to be **investigational\***.

## **Background/Overview**

### **Transcatheter Embolization**

Transcatheter 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. Uterine artery embolization has also been used to treat other conditions including postpartum hemorrhage (PPH) and cervical ectopic pregnancy.

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.

Uterine artery embolization has also been used to control bleeding in other situations such as severe PPH or in the treatment of cervical ectopic pregnancy.

### **Laparoscopic Occlusion**

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. Laparoscopic bipolar



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occlusion of the uterine vessels is a technique that was developed to directly devascularize the uterine fibroid. It potentially serves as an alternative to hysterectomy and to uterine artery embolization.

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 is laparoscopic bipolar coagulation of the uterine vessels which has been investigated as an alternative to UAE.

## **FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

In April 2000, Embosphere<sup>®</sup> † Microspheres (Biosphere Medical) were cleared for marketing by the U.S. FDA through the 510(k) process for hypervascularized tumors and arteriovenous malformations (AVMs). 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<sup>®</sup> Emboli PVA (Boston Scientific) was cleared for the embolization of peripheral hypervascular tumors and peripheral AVMs. In March 2004, the Contour SE<sup>™</sup> † (Boston Scientific) was cleared by the 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.

No devices have specific clearance/approval from the FDA for laparoscopic bipolar occlusion of the uterine vessels.

## **Rationale/Source**

### **Transcatheter Embolization**

The policy is based in part on a 2002 Technology Evaluation Center (TEC) Assessment and was updated regularly with literature searches. Following is a summary of the key literature to date on UAE therapy.

### **Uterine Artery Embolization for treatment of Uterine Fibroids**

#### **Uterine Artery Embolization Compared to Surgery**

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. Pooled analyses did not find statistically significant differences in patient satisfaction with UAE or surgery after 2 years (odds



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ratio [OR]: 0.69, 95% confidence interval [CI]: 0.40 to 1.21, 5 trials) or 5 years (OR: 0.90, 95% CI: 0.45-1.90, 2 trials). Uterine artery embolization 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 and colleagues published a meta-analysis of RCTs comparing UAE and surgery for treating symptomatic uterine fibroids and presented up to 5-year follow-up data. The investigators identified 11 articles reporting on 5 RCTs. The overall intra-procedural and early post-procedural 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 to the surgery group. At 12 months, a pooled analysis of 2 studies found a significantly higher reintervention rate in the UAE group compared to 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 and colleagues focused on complication and reintervention rates following UAE for symptomatic uterine fibroids. Eight RCTs comparing UAE to another intervention were included. Among the 350 UAE cases in the RCTs, the most common complications were discharge and fever (4%), post-embolization 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 to 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 below:

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). 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. 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 one woman had both a repeat UAE and a hysterectomy, and 2 women were not embolized after randomization and subsequently underwent surgery.

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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). 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 (HRQOL) 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. 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 (ITT) 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 HRQOL at 5 years, as assessed by mental and physical components of the Short Form-36 (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 of 6.87) compared to 2 years (mean of 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. 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;  $p < 0.0001$ ). 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 and colleagues 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. 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' post-intervention, 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). The cumulative clinical failure and recurrence rate was significantly lower for patients in the UAE group (17%, n = 5) compared to the laparoscopy group (48%, n = 17),  $p = 0.02$ . Moreover, fewer patients in

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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 UAO 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 to 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 Uterine Artery Embolization to Treat Recurrent or Persistent Symptoms*

No RCTs focusing on repeat UAE were identified. In 2009, McLucas and colleagues published a study in which the charts of 1,058 women who had undergone initial bilateral UAE at several U.S. centers were reviewed. 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 individuals experienced severe levels of one or more symptoms after the second UAE. Prospective comparative studies are needed to confirm the findings.

In 2006, Yousefi and colleagues reported on 24 patients who underwent repeat embolization for recurrent or persistent symptoms 6-66 months after the initial procedure. 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.

### **Uterine Artery Embolization for treatment of Postpartum Uterine Hemorrhage (PPH)**

No RCTs or other comparative studies evaluating UAE for treating PPH were identified. Several case series have been published. Representative larger series are described below:

### **Representative larger case series are described below:**

In 2011, Ganguli and colleagues published data on 66 women who underwent UAE for the treatment of postpartum hemorrhage. 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: one case of lower-extremity deep vein thrombosis, one case of postprocedural pancreatitis, and one admission for intravenous antibiotic treatment for presumed



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endometritis. Nine pregnancies after UAE were identified; there were 2 spontaneous abortions and 7 viable gestations.

In 2009, Kirby and colleagues published a retrospective analysis of data from 43 women who underwent UAE for primary PPH. 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 prior to 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 one case of a groin hematoma, one inadvertent perforation of the left obturator artery during UAE, one bleeding necrotic fibroid tumor, and one 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.

### **Uterine Artery Embolization 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 and colleagues. Patients underwent UAE and in conjunction with methotrexate injections before, during, and after the UAE procedure. Median follow-up was 12 months (range 1 to 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 human chorionic gonadotropin ([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.

### **Impact of Uterine Artery Embolization Treatment on Fertility and Pregnancy Outcomes**

A 2013 systematic review by Mohan and colleagues identified 21 studies reporting pregnancy outcomes and/or pregnancy complications after UAE for treatment of uterine fibroids or postpartum hemorrhage. 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 PPH, 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 PPH. Most of the studies included in the systematic review were observational



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and had no or inadequate controls. There was only one RCT. This study, by Mara and colleagues in Czech Republic, randomized 121 women with uterine fibroids who desired future pregnancies to UAE or myomectomy. 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 to 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%.

Previously, a 2010 systematic review was published that identified a total of 227 pregnancies after UAE for uterine fibroids from 8 published reports. Miscarriage rates were compared to a control group of 1,121 pregnancies in women with intramural fibroids from 14 studies. The overall pooled miscarriage rate was 80 of 227 (35.2%) in the UAE group compared to 185 of 1,121 (16.5%) in the fibroid group,  $p < 0.001$ . In addition, the review compared obstetric outcomes in women with UAE to a control group of 4,454 women from 10 studies on pregnancies complicated by fibroids. The rate of Cesarean section was significantly higher in the UAE group (66%) than in the fibroid group (48.6%),  $p < 0.001$ . There was also a significantly higher rate of PPH in the UAE group compared to the fibroid group, 14% versus 2.5%,  $p < 0.001$ . Rates of preterm delivery, malpresentation, and intra-uterine growth retardation (IUGR) did not differ significantly between groups.

### Section Summary:

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

### **Ongoing Clinical Trials**

The FIRSST: Comparing MRgFUS (MR guided Focused Ultrasound) versus UAE (Uterine Artery Embolization) (NCT00995878): This is an RCT comparing MRgFUS to 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): This RCT is testing the safety and efficacy of HIFU compared to 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 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 to surgery. Although there are a lack of controlled studies on repeat UAE,



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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 one repeat UAE to treat persistent symptoms may be considered medically necessary.

There are no controlled studies evaluating UAE for PPH or cervical ectopic pregnancy. However, due to available evidence from case series and strong support from clinical reviewers, UAE for PPH may be considered medically necessary. In the absence of either controlled studies or strong clinical support, UAE for management of cervical ectopic pregnancy is considered investigational.

### Laparoscopic Occlusion

Following is a summary of the literature on laparoscopic occlusion for treatment of uterine fibroids:

No RCTs were identified that compared laparoscopic uterine artery occlusion (UAO) to surgery. The literature searches retrieved two European cohort studies (n = 21 and n = 114) on laparoscopic occlusion. Both studies are limited due to a lack of appropriate controls. A retrospective evaluation of the complications and recurrence rate from the study of 114 patients found a 7.1% complication rate with a rate of fibroid recurrence of 9%. The recurrence-free survival rate at a median of 23.6 months follow-up was 88.3%.

Two randomized controlled trials were identified comparing transcatheter UAE and laparoscopic UAO. The larger study with longer follow-up was by Hald and colleagues and was conducted at a university hospital in Norway. The investigators 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. Women who wanted to bear children in the future, who had a large uterus, who 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, p = .96). Among the secondary outcomes, fewer participants in the group treated with UAE complained of heavy bleeding after 6 months (4% compared with 21%, p = .044). The postoperative use of ketobemidone was higher after UAE (46mg compared with 12mg, p < .001). Further treatment was required in a similar number of patients in each group (24% and 21%, respectively). An additional publication reported on follow-up data at a median of 48 months after treatment (range = 8-73 months). The cumulative clinical failure and recurrence rate was significantly lower for patients in the UAE group (17%, n = 5) compared to 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 UAO for treatment of uterine fibroids.

A smaller RCT was conducted in India; 20 women with symptomatic fibroids were randomized to UAE (n = 10) or laparoscopic UAO (n = 10). The primary outcome was symptomatic improvement in blood loss, measured by pictorial blood loss assessment charts. The groups were unbalanced at baseline—the pictorial



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blood loss was significantly higher in the laparoscopy group compared to the UAE group. The mean reduction in the blood loss score 3 months and 6 months postintervention did not differ significantly between groups. At 6 months, the percent reduction in blood loss scores was 60% in the UAE group and 41% in the laparoscopy group,  $p = 0.44$ . The subjective pain score at day 1 after surgery, a secondary measure, was significantly greater in the UAE group compared to the laparoscopy group (mean scores of 6.5 and 2.7, respectively, on a visual analogue scale). Although blood loss was similar in the two groups, the sample size was too small to draw accurate conclusions about the comparative efficacy of the procedures.

### Impact on Fertility and Pregnancy Outcomes

No studies were identified that evaluated pregnancy outcomes following laparoscopic occlusion.

### Summary

There is insufficient evidence on health outcomes associated with laparoscopic occlusion of the uterine arteries; data are lacking on outcomes compared to surgery, long-term outcomes and impact on subsequent fertility and pregnancy. Thus, laparoscopic occlusion for the treatment of uterine fibroids is considered investigational.

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## Occlusion of Uterine Arteries Using Transcatheter Embolization or Laparoscopic Occlusion to Treat Uterine Fibroids

Policy # 00130

Original Effective Date: 03/25/2002

Current Effective Date: 11/20/2013

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Code Type	Code
CPT	37204, 37210
HCPCS	No code
ICD-9 Diagnosis	218.0 thru 218.9, 666.0 thru 666.2
ICD-9 Procedure	68.25

### Policy History

Original Effective Date: 03/25/2002  
Current Effective Date: 11/20/2013

04/15/2003 Medical Policy Committee review  
05/12/2003 Managed Care Advisory Council approval  
05/04/2004 Medical Director review  
05/18/2004 Medical Policy Committee review. Format revision. Clinical criteria revision.  
06/28/2004 Managed Care Advisory Council approval  
06/07/2005 Medical Director review  
06/21/2005 Medical Policy Committee review. Format revision. Patient selection criteria added. Clinical criteria revision to include laparoscopic closure of uterine arteries. Policy title changed from, "Transcatheter Uterine Artery Embolization" to "Occlusion of Uterine Arteries Using Transcatheter Embolization or Laparoscopic Occlusion to Treat Uterine Fibroids".

07/15/2005 Managed Care Advisory Council approval  
07/07/2006 Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.

09/06/2006 Medical Director review  
09/20/2006 Medical Policy Committee approval. No change to policy guidelines.  
11/07/2007 Medical Director review  
11/15/2007 Medical Policy Committee approval. No change to policy guidelines.  
11/05/2008 Medical Director review  
11/18/2008 Medical Policy Committee approval. No change to coverage eligibility.  
11/12/2009 Medical Policy Committee approval  
11/18/2009 Medical Policy Implementation Committee approval. No change to coverage eligibility.  
11/04/2010 Medical Policy Committee approval  
11/16/2010 Medical Policy Implementation Committee approval. No change to coverage eligibility.  
11/03/2011 Medical Policy Committee approval  
11/16/2011 Medical Policy Implementation Committee approval. No change to coverage eligibility.  
11/01/2012 Medical Policy Committee review  
11/28/2012 Medical Policy Implementation Committee approval. Postpartum uterine hemorrhage added to eligible for coverage statement. Investigational statement added on UAE for management cervical ectopic pregnancy. Statement on repeat UAE changed to state that one repeat procedure may be considered eligible for coverage with a *Note* following the coverage statement.

11/07/2013 Medical Policy Committee review  
11/20/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
Next Scheduled Review Date: 11/2014

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\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  3. reference to federal regulations.

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- A. in accordance with nationally accepted standards of medical practice;
- B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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