



# Louisiana

## 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:** 02/21/2018

*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 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 all other indications, including cervical ectopic pregnancy, uterine arteriovenous malformation, and adenomyosis to be **investigational**.\*

### **Background/Overview**

Uterine leiomyomata (ie, fibroids) are extremely common benign tumors that can be submucosal (located primarily within the uterine cavity below the endometrium), intramural (with the uterine wall or myometrium), or subserosal in location. Patient symptomatology, physical examination findings, and imaging results are related to the location of the fibroids. Individuals may have fibroids in any or all of these locations within the uterus.

### **Treatment**

Treatment for uterine fibroids is usually sought when they are associated with menorrhagia, pelvic pain, urinary symptoms (ie, frequency), or are suspected to cause infertility. Treatment options include medical therapy with gonadotropin agonists or progestins or various types of surgical therapy. Hysterectomy is considered the definitive surgical treatment for those who no longer want to maintain fertility. Various types of myomectomy, which describes the removal of fibroids with retention of the uterus, have also been described. Hysteroscopic myomectomy involves removal of submucosal fibroids using 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 fibroid are performed to devascularize the fibroid and induce atrophy.

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

Ectopic pregnancies account for up to 2% of pregnancies and are the leading cause of first-trimester maternal mortality. Patients present with pelvic pain and vaginal bleeding. First-line treatment for patients with minimal symptoms is systemic methotrexate. In patients with high  $\beta$ -human chorionic gonadotrophin,

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response to methotrexate may not be adequate, and the patient is susceptible to complications such as hemorrhaging, resulting in the need for a hysterectomy.

Uterine AVMs are rare but may cause severe genital hemorrhaging. There are two types: low-flow AVM is characterized by an abnormal vascular network without visible early venous drainage and high-flow AVM, which has early venous drainage. Uterine AVMs may be congenital or acquired. Risk factors for acquired AVMs are prior uterine surgery such as dilatation and curettage, myomectomy, and cesarean section. Treatment options include hysterectomy, uterine artery ligation, and uterine artery embolization.

Adenomyosis is characterized by the diffuse or focal growth of endometrial glandular and stromal tissue in the muscular layer of the uterus. The etiology of adenomyosis is unknown. Symptoms include dysmenorrhea, menorrhagia, infertility, and an enlarged uterus may be found on physical examination. Treatment options include surgery and hormone therapy.

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

U.S. Food and Drug Administration (FDA)

In April 2000, Embosphere<sup>®</sup> Microspheres (Merit Medical, formerly BioSphere Medical) was cleared for marketing by the U.S. FDA through the 510(k) process for hypervascularized tumors and AVMs. In November 2002, this product was cleared for marketing specifically for use in uterine fibroid embolization. Since then, several other devices have been cleared for marketing. In 2003, Contour<sup>®</sup> Emboli PVA (Boston Scientific) was cleared for marketing by FDA through the 510(k) process for the embolization of peripheral hypervascular tumors and peripheral AVMs. In March 2004, the Contour SE<sup>™</sup> (Boston Scientific) was also cleared for marketing by FDA through the 510(k) process for treatment of uterine fibroids. In December 2008, Polyvinyl Alcohol Foam Embolization Particles (Cook Inc.) was cleared for marketing by FDA through the 510(k) process for use in uterine fibroid embolization. FDA product code: NAJ.

### **Rationale/Source**

Assessment of efficacy for therapeutic intervention involves a determination of whether the intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition.

### **UAE FOR TREATMENT OF UTERINE FIBROIDS**

#### **Initial UAE Procedure for Uterine Fibroids**

A number of RCTs evaluating UAE for the treatment of uterine fibroids and several systematic reviews of these RCTs have been published. RCTs have compared UAE with hysterectomies, myomectomies, laparoscopic occlusion of uterine arteries, and focused ultrasound.

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### **Systematic Reviews**

A 2014 Cochrane review included 7 RCTs comparing UAE with other surgical interventions in women with symptomatic uterine fibroids. Four of the RCTs excluded women who desired pregnancy in the future. The comparator intervention was hysterectomy in 3 trials, hysterectomy or myomectomy in 2 trials, and myomectomy in 2 trials. Reviewers' primary outcomes were patient satisfaction and live birth rates (the latter analysis limited to studies where the comparison intervention was a uterine-sparing procedure). Pooled analyses did not find statistically significant differences in patient satisfaction with UAE or other interventions after 2 years (6 trials; odds ratio [OR], 0.94; 95% confidence interval [CI], 0.59 to 1.48) or 5 years (2 trials; OR=0.90; 95% CI, 0.45 to 1.80). A single study reported live birth rates, so a meta-analysis was not possible. UAE was associated with a higher rate of minor complications at 1 year (6 trials; OR=1.99; 95% CI, 1.41 to 2.81), and there was no statistically significant difference between groups in the rate of major complications. Moreover, the UAE group was significantly less likely to require a blood transfusion than the surgery group (2 trials; OR=0.07; 95% CI, 0.01 to 0.52). The rate of further surgical interventions within 2 years was significantly increased in the UAE group (6 trials; OR=3.72; 95% CI, 2.28 to 6.04).

In a 2014 systematic review and meta-analysis, Das et al identified 10 studies comparing the efficacy of 1 embolic agent used in UAE with another intervention or comparing 2 embolic agents. Five studies were RCTs, and five were controlled trials that were not randomized. Embosphere microspheres were used in all of the RCTs. In a pooled analysis of data from 2 studies comparing microspheres with spherical polyvinyl alcohol for the treatment of uterine fibroids, there were no statistically significant between-group differences in outcomes (uterine volume reduction, 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 superior or inferior to any other agent.

A 2013 systematic review and meta-analysis by Martin et al focused on comparing complications and reintervention rates following UAE and surgery for symptomatic uterine fibroids. Surgery was not defined in this meta-analysis, so it is unclear whether myomectomies were also included with hysterectomies. Outcomes for UAE and surgery were stratified by study design (RCTs, nonrandomized studies, case series). Eight RCTs comparing UAE with a surgical intervention were included, for a total of 350 patients undergoing UAE and 346 patients undergoing surgery. Among the 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%). The most common complications among patients undergoing 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 than after surgery, but a wide confidence interval indicates imprecision in the risk estimate (OR=6.04; 95% CI, 2.0 to 18.1).

In 2011, van der Kooij et al published a systematic review and meta-analysis of RCTs comparing UAE with surgery (hysterectomy/myomectomy) for treating symptomatic uterine fibroids and presenting up to 5 years

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of follow-up data. Reviewers identified 11 articles reporting on 5 RCTs. The overall intraprocedural and early postprocedural complication rates were similar with both procedures. However, hospital length of stay, need for blood transfusion, and febrile morbidity was significantly lower in the UAE group than in the surgery group. At 12 months, a pooled analysis of 2 studies found a significantly higher reintervention rate in the UAE group than in the surgery group (OR=5.78; 95% CI, 2.14 to 15.58). Pooled analyses of quality of life (QOL) variables at 12 months found no significant differences between groups. Results were similar after 5 years. The reintervention rate was significantly higher in the UAE group at 5 years, based on pooled analysis of 2 trials (OR=5.41; 95% CI, 2.48 to 11.81).

### **Randomized Controlled Trials**

#### *UAE vs Hysterectomy or Myomectomy*

The multicenter Randomized Trial of Embolization vs Surgical Treatment for Fibroids (REST) assigned patients 2:1 to undergo UAE (n=106) or surgery (n=43 hysterectomies, n=8 myomectomies). The UAE group had lower postoperative pain (3.0 vs 4.6, respectively) and faster recovery (eg, median length of hospitalization, 1-day vs 5-day, respectively). Of seven identified pregnancies in the UAE group, two resulted in successful live births. Five-year follow-up data from the REST trial were published in 2011. A total of 144 (92%) of 157 randomized patients were included in the 5-year analysis. QOL and symptom scores were similar in both groups at 5 years: 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]). At 5-year follow-up, 27 (25%) of 106 in the UAE group and 2 (4%) of 51 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 procedural failures, 8 repeat UAEs, and 18 hysterectomies. Note that a 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 UAE (n=88) or hysterectomy (n=89). By the 2-year follow-up, 19 (23%) of the 81 women who received UAE had undergone a hysterectomy. An analysis of health-related QOL outcomes at 2 years found similar improvement in both groups. The Defecation Distress Inventory score improved significantly in only the UAE group starting at 6 months. A report of 5-year outcomes data from the EMMY trial was published in 2010. At 5 years, 70 (79%) of 89 patients originally randomized to the hysterectomy group and 75 (85%) of 88 patients in the UAE group completed questionnaires. In an intention-to-treat analysis, 23 (28.4%) of 81 patients who had received UAE underwent hysterectomy during the 5 years. Including patients who had subsequent hysterectomies, 58 (71.6%) of 81 patients in the UAE group no longer had menorrhagia. There were no significant differences between groups in health-related QOL at 5 years, as assessed by the Physical and Mental Component scores of the 36-Item Short-Form Health Survey. Ten-year outcomes were reported by de Bruijn et al in 2016. Completed questionnaires were available for 131 (75%) of 177 randomized patients at 10 years. An additional 5 hysterectomies were performed between the

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5- and 10-year follow-ups, for a total of 28 (35%) hysterectomies in the UAE group. At 10 years, there were no statistically significant differences between groups in health-related QOL or in urinary and defecation function.

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 (2 days) than after surgery (4 days;  $p < 0.001$ ). There were no significant differences in minor or major complications. A total of 120 (74%) of 163 women were available for the analysis of the primary outcome measure (QOL). There were no significant differences between groups in change in QOL scores from baseline to 1 year. Nine (11%) patients in the UAE group required additional intervention (6 hysterectomies, 2 myomectomies, 1 repeat embolization) and 3 (4%) patients in the myomectomy group later underwent hysterectomy.

### *UAE vs Laparoscopic Occlusion of Uterine Arteries*

An RCT by Hald et al (2007) in Norway evaluated clinical outcomes in 66 premenopausal women (mean age, 43 years) with symptomatic uterine fibroids who were assigned to laparoscopic occlusion of uterine arteries or UAE. Women who wanted to bear children in the future, had a large uterus, had undergone multiple open abdominal surgeries, and who had bleeding disorders were excluded. The primary outcome was a reduction in blood loss at 6 months postintervention, as measured by a pictorial blood loss assessment chart. Fifty-eight women underwent treatment, 29 in each group. The proportion of women who had a reduction in blood loss after 6 months did not differ between the treatment groups (52% after UAE vs 53% after laparoscopy;  $p = 0.96$ ). Follow-up data were reported in 2009 at a median of 48 months posttreatment (range, 8-73 months). The cumulative clinical failure and recurrence rate was significantly lower in the UAE group (17% [n=5]) than in 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.

### *UAE vs Focused Ultrasound*

In 2017, Barnard et al published an RCT and a cohort study comparing the use of UAE with magnetic resonance imaging-guided focused ultrasound surgery (MRgFUS) for the treatment of uterine fibroids. Premenopausal women with symptomatic uterine fibroids were randomized to MRgFUS (n=27) or UAE (n=22). Women who declined randomization were enrolled in a nonrandomized cohort study; 43 underwent MRgFUS, and 40 underwent UAE. The outcome of interest was recovery during the first 6 weeks postprocedure, captured in symptom diaries that included information on return to work, return to normal activities, medication use, symptoms, and adverse events. Separate multivariate analyses of the RCT and the cohort populations found similar conclusions: opioid use was significantly higher in the UAE group, and length of time to first day fully back to work and first day back to normal activities were also significantly longer for patients treated with UAE. Treatment time was significantly longer in the MRgFUS group.

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### **Section Summary: Initial UAE Procedures for Uterine Fibroids**

Most of the current evidence, including a number of RCTs and systematic reviews, has compared UAE with surgery (hysterectomy or myomectomy) for treating uterine fibroids. A Cochrane review found similar levels of patient satisfaction after UAE and surgery. A potential benefit of UAE over hysterectomy is that, depending on the location of the fibroids, the uterus and fertility may be preserved. Other benefits of UAE over hysterectomy and/or myomectomy include lower blood transfusion rates and lower complication rates. However, studies with long-term follow-up have shown that patients undergoing UAE have higher reintervention rates. Single RCTs have compared UAE with laparoscopic occlusion and MRgFUS. UAE had higher clinical success rates and lower reintervention rates than laparoscopic occlusion. Recovery was longer and opioid use higher among patients undergoing UAE compared with MRgFUS. Additional research comparing other uterus-sparing procedures with UAE are needed. The available evidence from RCTs does not suggest that any one embolization agent is superior to another.

### **Repeat UAE Procedures for Recurrent or Persistent Uterine Fibroid Symptoms**

No RCTs focusing on repeat UAE were identified; there are published case series. In 2009, McLucas and Reed published a study in which the charts of 1058 women who had undergone initial bilateral UAE at several U.S. centers were reviewed. Forty-two (4%) patients had documented persistent symptoms, and they were offered a second bilateral UAE. Thirty-nine patients had repeat procedures, and 34 (87%) of them completed a follow-up questionnaire at least 6 months postembolization. Before the second UAE procedure, 27 (79%) of the 34 women reported severe bleeding, with only 2 (6%) women reported severe bleeding postprocedure. 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%). Four women experienced severe levels of one or more symptoms after the second UAE.

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 UAE. 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 (87.5%) of 24 after the second UAE; 19 (90%) reported symptom control.

### **Section Summary: Repeat UAE Procedures for Recurrent or Persistent Uterine Fibroid Symptoms**

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

### **UAE FOR POSTPARTUM UTERINE HEMORRHAGE**

No RCTs or other comparative studies evaluating UAE for treating postpartum hemorrhage were identified. Several systematic reviews of the literature on treatments for postpartum hemorrhage have been published.

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### Systematic Reviews

In 2016, Sathe et al reported that rates of successful bleeding control with UAE in uncontrolled studies ranged from 58% to 98%, with a total of 1251 (87%) of 1435 patients in 15 studies achieving successful control of bleeding.

Previously, in 2012, Rath et al published a systematic review of the literature on second-line treatment of postpartum hemorrhage. Success rates of UAE for postpartum hemorrhage reported in uncontrolled studies ranged from 70% to 100% and from 60% to 83% when the hemorrhage was associated with placenta accreta.

### Case Series

Among the representative, larger case series is the 2013 retrospective evaluation by Kim et al of data on 121 women with postpartum hemorrhage, 60 women of whom underwent UAE and 61 of whom underwent a cesarean hysterectomy at a single center in Korea. The clinical success rate for UAE (which was not explicitly defined) was reported as 96%. Eleven patients treated with UAE experienced transient fever after the procedure, and there was a case of ovarian failure. Two patients were subsequently treated with cesarean hysterectomy. Among the 61 patients at the same center who underwent cesarean hysterectomy, the success rate was 93%. Four patients in this group underwent UAE immediately following cesarean hysterectomy due to arterial hemorrhage at extrauterine sites (2 cases) and bleeding from uterine collateral vessels (2 cases).

In 2011, Ganguli et al 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 (5%) of 66 women had a subsequent hysterectomy. In addition to the 3 clinical failures, there were 3 (5%) major complications after UAE: one case each of lower-extremity deep vein thrombosis, postprocedural pancreatitis, and presumed endometritis. Nine pregnancies after UAE were identified; there were two spontaneous abortions and seven viable gestations.

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

### Section Summary: UAE for Postpartum Uterine Hemorrhage

There is a lack of RCTs or other controlled studies on UAE for the treatment of postpartum hemorrhage. Case series involving totaling over 1400 patients have shown a high rate of successfully stopping the

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bleeding. Without treatment, there is a high likelihood of significant ongoing hemorrhage and maternal mortality. Given that this is an emergent, often clinically complex situation that can result in maternal mortality, it may not be practical to conduct RCTs and positive case series data may suffice.

### **FERTILITY AND PREGNANCY OUTCOMES AFTER UAE FOR UTERINE FIBROIDS OR POSTPARTUM HEMORRHAGE**

Several systematic reviews and an RCT on fertility and pregnancy outcomes after UAE have been published.

In 2014, Doumouchsis et al identified 17 studies (total N=675 participants) reporting on fertility outcomes after UAE for postpartum hemorrhage. To be selected, studies had to report on 5 or more cases. None identified was an RCT. A total of 168 (25%) of the 675 patients wanted a pregnancy following UAE and 126 (75%) of the 168 women who desired pregnancy conceived. There were 136 term live births and 30 cases of pregnancy loss (ectopic pregnancy, miscarriage, elective abortion).

In 2013, Mohan et al identified 21 studies reporting pregnancy outcomes and/or pregnancy complications after UAE for the treatment of uterine fibroids or postpartum hemorrhage. Reviewers reported that the cumulative pregnancy and miscarriage rates among women trying to conceive following UAE for uterine fibroids were 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 studies included in the systematic review were observational and had no or inadequate controls. The single RCT identified is described below.

In 2008, Mara et al conducted an RCT, randomizing 121 women with uterine fibroids who desired future pregnancies to UAE or myomectomy. Participants were followed for a mean of 25 months; they were advised to wait for at least 6 months postprocedure before attempting to conceive. At final follow-up, 13 (50%) of 26 women in the UAE group who tried to conceive became pregnant compared with 31 (76%) of 40 in the myomectomy group; the difference between groups was not statistically significant. Among women in the UAE group who became pregnant, the spontaneous abortion rate was 64%, and the live birth rate was 19%. In the myomectomy group, the spontaneous abortion rate was 23%, and the live birth rate was 48%.

### **Section Summary: Fertility and Pregnancy Outcomes After UAE for Uterine Fibroids or Postpartum Hemorrhage**

Reviews of fertility and pregnancy outcomes after UAE have suggested that successful pregnancy is possible after UAE for the treatment of uterine fibroids or postpartum hemorrhage. One review found higher rates of miscarriage and postpartum hemorrhage with UAE than with myomectomy, though the numbers in each group trying to conceive were small. There are limited data on pregnancy outcomes in women who became pregnant following UAE for the treatment of postpartum hemorrhage.

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### **UAE FOR CERVICAL ECTOPIC PREGNANCY**

No RCTs or other comparative studies evaluating UAE for treating cervical ectopic pregnancy were identified. The published literature consisted of small case series. Sample sizes ranged from 2 to 20 patients, and most studies had fewer than 10 patients.

In 2017, Kwon et al retrospectively reviewed the charts of 13 women who had ectopic pregnancies that were refractory to systemic methotrexate who were then treated with UAE. Locations of the ectopic implantation were: cesarean scar (n=6), cervix (n=5), fallopian tube (n=1), and uterine cornua (n=1). Outcomes were technical success, clinical success, and complications. Results were reported for all patients, regardless of the ectopic implantation site. Mean gestational age at the time of diagnosis was 8.5 weeks (range, 3-14 weeks). Median follow-up was 25 weeks (range, 4-85 weeks). Technical success was 100%. Clinical success was achieved in 10 (77%) patients. Three patients experienced recurrent vaginal bleeding (2 instances of which occurred in patients who had cervical ectopic pregnancies) and underwent repeat embolizations. The uteri of all 13 patients were preserved.

Hu et al (2016) retrospectively reviewed the charts of 19 women who had cervical pregnancies and were treated with UAE followed by curettage. The median gestational age of the fetuses at the time of UAE was 7.4 weeks (standard deviation, 1.6). One procedure was deemed an emergency due to profuse bleeding; the remaining 18 were nonemergency procedures. There were no reports of further vaginal bleeding following UAE. None of the patients underwent a hysterectomy due to the cervical pregnancy. Nine patients were followed for up to 39 months. Eight of the nine resumed normal menstruation. Only one attempted to conceive, and she had an uncomplicated pregnancy and a vaginal delivery.

The largest prospective series was conducted in China by Xiaolin et al (2010). Patients received methotrexate injections before, during, and after the UAE procedure. Median follow-up was 12 months (range, 1-50 months). Two (10%) of 20 patients had recurrent vaginal bleeding; the other 18 had no significant bleeding after UAE. Five (25%) patients had an additional curettage procedure due to bleeding and/or high levels of  $\beta$ -human chorionic gonadotropin. The uterus was preserved in all patients, and normal menses resumed after 2 to 4 months. Eight (50%) of 16 women who attempted to conceive achieved a normal pregnancy within 1 year. There were 2 miscarriages and 6 live births at term.

### **Section Summary: UAE for Cervical Ectopic Pregnancy**

Cervical ectopic pregnancy is an emergent, rare, and clinically complex situation that may preclude gathering controlled data for evidence. However, because there are only a few case series available, the largest of which included 20 patients, additional case series are needed to inform a determination of efficacy. The limited noncomparative evidence is insufficient to determine the effect of UAE on health outcomes.

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# Louisiana

## 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: 02/21/2018

### **UAE FOR UTERINE ARTERIOVENOUS MALFORMATION**

No RCTs or other comparative studies evaluating UAE for treating uterine AVMs were identified. The published literature consists of case reports, small case series, and a systematic review.

#### **Systematic Reviews**

A 2016 systematic review by Yoon et al of literature on acquired uterine AVMs identified 54 women treated with UAE in 40 studies published between 2003 and 2013, primarily case reports. There were 22 unilateral and 32 bilateral procedures. Thirty-three (61%) of 54 patients had symptoms controlled with the initial embolization procedure. Nine of 13 patients who underwent repeat UAE experienced resolution of symptoms. No major complications were reported after UAE.

#### **Case Series**

The following case series were published since the Yoon systematic review. In 2017, Barral et al described using ethylene vinyl alcohol copolymer (Onyx) as the embolic agent for UAE in the treatment of uterine AVMs. Records from 12 women, mean age 33 years, were reviewed. After a mean follow-up of 29 months, 11 of the 12 women achieved clinical success, defined as the absence of bleeding at 1 month following embolization.

The largest 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 AVMs. 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. Seventeen (89.5%) of 19 patients had immediate clinical success following the UAE, defined as cessation of bleeding without symptom recurrence and resolution of the uterine AVMs on postoperative imaging studies.

#### **Section Summary: UAE for Uterine Arteriovenous Malformation**

The limited noncomparative evidence is insufficient to determine the effect of UAE on health outcomes in patients with bleeding associated with uterine AVMs. Additional data, ideally controlled trials comparing UAE with alternative uterine-sparing treatments, are needed to determine the safety and efficacy of UAE for treating uterine AVMs.

### **UAE FOR ADENOMYOSIS**

No RCTs or other comparative studies evaluating UAE for treating adenomyosis were identified.

#### **Systematic Reviews**

In a 2011 systematic review of publications from 1999 through 2010, Popovic et al evaluated the literature on UAE for patients with adenomyosis, alone or in conjunction with uterine fibroids. Reviewers identified 8 case series reporting short-term follow-up in patients with adenomyosis alone. After a median follow-up of 9.4 months (range, 3-12 months), 85 (83%) of 102 patients had marked or complete improvement in clinical symptoms. Six case series reported long-term follow-up (median, 40.6 months; range, 17-60 months).

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Marked or complete improvement occurred in 135 (65%) of 208 patients, suggesting recurrence of symptoms over time in some patients. No deaths or serious adverse events were reported.

### Case Series

Additional case series have been published since the Popovic systematic review. In 2017, de Bruijn et al provided 7-year QOL data on 28 women with adenomyosis treated with UAE. Outcomes were Uterine Fibroid Symptom Quality of Life (UFS-QOL) questionnaire and Symptom Severity Score (SSS). A higher UFS-QOL score indicates a better QOL and a lower SSS indicates an improvement in symptoms. Patients were considered asymptomatic if their SSS was less than 20 and their UFS-QOL score was greater than 80. At 7 years posttreatment, 3 women had undergone a second UAE, and 5 women had undergone a secondary hysterectomy. Median SSS at baseline was 72 (range, 23-100) and improved to 17 (range, 0-44). Median UFS-QOL score at baseline was 31 (range, 20-88) and improved to 98 (range, 9-100).

In 2016, Zhou et al evaluated short- (12-month) and long-term (5-year) outcomes for 252 women following UAE treatment for adenomyosis. Outcomes of interest were dysmenorrhea and menorrhagia. Subgroup analyses were conducted by lesion vascularity: (1) blood supply equality of the uterus ("equal" if left and right uterine arteries supplied blood equally, otherwise "unequal") and (2) vascularity degree ("hypervascular" if vessels abundant at margin and center of lesions, "isovascular" if vessels abundant at margin but not core, and "hypovascular" if vessels lacking at margin and core). Following UAE, both short- and long-term rates of dysmenorrhea improvement and menorrhagia improvement were statistically similar among the equal and unequal blood supply groups, with improvement rates reported between 68% and 77%. However, improvement rates in dysmenorrhea and menorrhagia differed statistically among the vascularity groups, with patients in the hypervascular group experiencing higher rates of improvement than the other groups.

In 2016, Wang et al prospectively reported on 117 premenopausal patients with adenomyosis who underwent UAE. A total of 115 (98%) of 117 patients who successfully underwent bilateral UAE were included in the analysis. At 12 months, patients were queried about change in dysmenorrhea symptoms. Thirteen (11.3%) patients reported slight symptom improvement, 64 (55.7%) reported moderate improvement, and 31 (27.0%) reported marked improvement. Seven (6%) patients reported no change.

In 2015, Bae et al retrospectively reviewed outcomes for 50 women who underwent UAE for symptomatic adenomyosis and were followed for at least 18 months. At baseline, 41 (82%) of 50 women had both heavy menstrual bleeding and dysmenorrhea; the remainder reported only 1 of these 2 symptoms. The extent of postprocedure necrosis of adenomyosis imaged with magnetic resonance imaging was significantly associated with the likelihood of experiencing symptoms at follow-up. In receiver operating characteristic curve analysis, a cutoff of 34.3% necrosis was the most predictive of symptom recurrence (area under the curve, 0.721; 95% CI, 0.577 to 0.839;  $p=0.004$ ). Among 12 patients with less than 34.3% necrosis, 58% were symptom-free at 18 months; among 40 patients with greater than 34.3% necrosis, 94% were symptom-free at 18 months.

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### Section Summary: UAE for Adenomyosis

There is a lack of RCTs or other controlled comparative studies on UAE for the treatment of adenomyosis. Several case series and a systematic review are available. The systematic review found short-term symptom improvement in 83% of patients and long-term improvement in 65% of patients. Preliminary evidence from case series published after the systematic review showed that patients with greater necrosis of adenomyosis and patients with higher vascularity of lesions had higher response rates to UAE. A case series with 7 years of follow-up reported that 5 (18%) of 28 patients underwent a subsequent hysterectomy. Additional data from controlled trials are needed, especially on long-term efficacy and recurrence rates.

### SUMMARY OF EVIDENCE

For individuals who have uterine fibroids who receive transcatheter UAE, the evidence includes randomized controlled trials and systematic reviews. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The majority of studies have compared UAE with hysterectomy and myomectomy and found similar levels of symptoms and quality of life across all treatment groups. Benefits for women undergoing UAE included avoiding surgery and maintaining their uteruses, lower complication rates, and lower blood transfusion rates. However, patients undergoing UAE had higher reintervention rates compared with patients who had surgery. Smaller trials have compared UAE with laparoscopic occlusion and magnetic resonance image-guided focused ultrasound surgery. Additional trials with larger sample sizes comparing UAE with these and other uterus-preserving procedures are needed. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have persistent uterine fibroids despite prior uterine artery embolization who receive repeat transcatheter UAE, the evidence includes case series. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. Case series have shown that a high degree of symptom relief is possible after a repeat UAE for uterine fibroids. Moreover, evidence from randomized controlled trials on the safety and efficacy of UAE for initial treatment of uterine fibroids may indicate a benefit for patients in need of repeat procedures for the same indication. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have postpartum uterine hemorrhage who receive transcatheter UAE, the evidence includes case series and a systematic review. Relevant outcomes are overall survival, symptoms, and treatment-related morbidity. The systematic review of case series assessing over 1400 women reported success rates of stopping bleeding that ranged from 58% to 98%. Postpartum uterine hemorrhage is an emergency situation with serious potential consequences (ie, maternal mortality). Conducting randomized controlled trials is particularly difficult in this setting and may be unnecessary when there are sufficient uncontrolled data. Though from case series, there is evidence reporting on over 1400 women. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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For individuals who have cervical ectopic pregnancy who receive transcatheter UAE, the evidence includes case series. Relevant outcomes are treatment-related morbidity. Only a few case series with a small number of patients have been published. Additional studies, especially controlled studies comparing UAE with medication or surgery, are needed to assess the safety and efficacy of UAE in patients with cervical ectopic pregnancy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have uterine arteriovenous malformations who receive transcatheter UAE, the evidence includes case reports, case series, and a systematic review. Relevant outcomes are symptoms, and treatment-related morbidity. Only case reports and case series with a small number of patients have been published. A systematic review identified 54 women in 40 studies with uterine arteriovenous malformations treated with UAE. Additional controlled studies comparing UAE with hysterectomy are needed to assess the safety and efficacy of UAE in patients with uterine arteriovenous malformations. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have adenomyosis who receive transcatheter UAE, the evidence includes case series and a systematic review. Relevant outcomes are symptoms, and treatment-related morbidity. A systematic review of case series data found short-term improvement in 83% of patients and long-term improvement in 65% of patients, suggesting possible recurrence of symptoms over time. All studies were case series, which might have been subject to selection and/or observational biases. Additional case series published after the review have reported that patients with greater necrosis of adenomyosis and patients with higher vascularity of lesions may experience higher response rates to UAE. Controlled studies comparing UAE with medication or surgery and studies reporting long-term symptom recurrence rates are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

### References

1. Blue Cross and Blue Shield Association, [Medical Policy Reference Manual](#), "Occlusion of Uterine Arteries Using Transcatheter Embolization", 4.01.11, 8:2017.
2. Blue Cross and Blue Shield Association, [Medical Policy Reference Manual](#), "Occlusion of Uterine Arteries Using Laparoscopic Occlusion to Treat Uterine Fibroids", 4.01.20 2:2011(Archived)
3. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Uterine artery embolization for treatment of symptomatic uterine fibroids. TEC Assessments 2002; Volume 17, Tab 8.
4. Gupta JK, Sinha A, Lumsden MA et al. Uterine artery embolization for symptomatic uterine fibroids. *Cochrane Database Syst Rev* 2012; 5:CD005073
5. 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
6. Martin J, Bhanot K, Athreya S. Complications and reinterventions in uterine artery embolization for symptomatic uterine fibroids: a literature review and metaanalysis. *Cardiovasc Intervent Radiol* 2013; 36(2):395-402.
7. Edwards RD, Moss JG, Lumsden MACotRTtoEvSTfF et al. Uterine-artery embolization versus surgery for symptomatic uterine fibroids. *N Engl J Med* 2007; 356(4):360-70.
8. Moss JG, Cooper CG, Khaund A et al. Randomised comparison of uterine artery embolisation (UAE) with surgical treatment in patients with symptomatic uterine fibroids (REST trial): 5-year results. *BJOG* 2011; 118(8):936-44.

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9. Hehenkamp WJ, Volkens 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.
10. Volkens 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.
11. van dKSM, Hehenkamp WJ, Volkens 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.
12. 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.
13. 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.
14. 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.
13. 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.
14. McLucas B, Reed RA. Repeat uterine artery embolization following poor results. *Minim Invasive Ther Allied Technol* 2009; 18(2):82-6.
15. 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
16. Das R, Champaneria R, Daniels JP et al. Comparison of Embolic Agents Used in Uterine Artery Embolisation: A Systematic Review and Meta-Analysis. *Cardiovasc Intervent Radiol* 2013.
17. Rath W, Hackethal A, Bohlmann MK. Second-line treatment of postpartum haemorrhage (PPH). *Arch Gynecol Obstet* 2012; 286(3):549-61.
18. Kim TH, Lee HH, Kim JM et al. Uterine artery embolization for primary postpartum hemorrhage. *Iran J Reprod Med* 2013; 11(6):511-8.
19. 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.
20. Kirby JM, Kachura JR, Rajan DK et al. Arterial embolization for primary postpartum hemorrhage. *J Vasc Interv Radiol* 2009; 20(8):1036-45
21. 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.
22. 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.
23. 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.
24. Mohan PP, Hamblin MH, Vogelzang RL. Uterine Artery Embolization and Its Effect on Fertility. *J Vasc Interv Radiol* 2013.
25. 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.
26. Sponsored by the Mayo Clinic. The FIRSST: Comparing MRgFUS (MR guided Focused Ultrasound) versus UAE (Uterine Artery Embolization) (NCT00995878). Available online at: [clinicaltrials.gov](http://clinicaltrials.gov). Last accessed May, 2014.
27. 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.
28. American College of Obstetricians and Gynecologists (ACOG). Committee Opinion No. 293: Uterine artery embolization. *Obstet Gynecol* 2004; 103(2):403-4.
29. 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.
30. 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.

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31. Barnard EP, AbdElmagied AM, Vaughan LE, et al. Periprocedural outcomes comparing fibroid embolization and focused ultrasound: a randomized controlled trial and comprehensive cohort analysis. *Am J Obstet Gynecol.* May 2017;216(5):500 e501-500 e511. PMID 28063909
32. Kwon JH, Kim GM, Han K, et al. Safety and efficacy of uterine artery embolization in ectopic pregnancies refractory to systemic methotrexate treatment: a single-center study. *Cardiovasc Intervent Radiol.* May 01 2017. PMID 28462440
33. Hu J, Tao X, Yin L, et al. Successful conservative treatment of cervical pregnancy with uterine artery embolization followed by curettage: a report of 19 cases. *BJOG.* Sep 2016;123 Suppl 3:97-102. PMID 27627607
34. Barral PA, Saeed-Kilani M, Tradi F, et al. Transcatheter arterial embolization with ethylene vinyl alcohol copolymer (Onyx) for the treatment of hemorrhage due to uterine arteriovenous malformations. *Diagn Interv Imaging.* May 2017;98(5):415-421. PMID 27776896
35. de Bruijn AM, Smink M, Hehenkamp WJK, et al. Uterine artery embolization for symptomatic adenomyosis: 7-year clinical follow-up using UFS-QoL Questionnaire. *Cardiovasc Intervent Radiol.* May 17 2017. PMID 28516272
36. Zhou J, He L, Liu P, et al. Outcomes in adenomyosis treated with uterine artery embolization are associated with lesion vascularity: a long-term follow-up study of 252 cases. *PLoS One.* Nov 2 2016;11(11):e0165610. PMID 27806072

### **Policy History**

Original Effective Date: 03/25/2002

Current Effective Date: 02/21/2018

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

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Policy # 00130  
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 Current Effective Date: 02/21/2018

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.

02/05/2015 Medical Policy Committee review

02/18/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.

02/04/2016 Medical Policy Committee review.

02/17/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

02/02/2017 Medical Policy Committee review.

02/15/2017 Medical Policy Implementation Committee approval. Adenomyosis and uterine arteriovenous malformation added to investigational policy statement.

02/01/2018 Medical Policy Committee review.

02/21/2018 Medical Policy Implementation Committee approval. Removed "Based on review of available data, the Company considers laparoscopic occlusion of the uterine arteries using bipolar coagulation to be investigational" from coverage statement.

Next Scheduled Review Date: 02/2019

### **Coding**

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Policy # 00130  
 Original Effective Date: 03/25/2002  
 Current Effective Date: 02/21/2018

HCPCS	No codes
ICD-10 Diagnosis	D25.0-D25.9, N80.0-N80.9, O00.80-O00.81, O43.211-O43.213, O43.221-O43.223, O43.231-O43.233, O72.0-O72.2, Q27.30, Q27.39

\*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 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
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  - 2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
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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.

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