Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. 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.
Description of Procedure or Service:
Transcatheter uterine artery embolization (UAE) is a minimally invasive technique that involves the injection of small particles into the uterine arteries to block the blood supply to the uterus and uterine fibroids. It potentially serves as an alternative to hysterectomy. UAE has also been used to treat other conditions including postpartum hemorrhage (PPH), cervical ectopic pregnancy and bleeding uterine arteriovenous malformation.

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

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

Policy:
Effective for dates of service on or after September 4, 2012:
Transcatheter embolization of uterine arteries as a treatment of uterine fibroids meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when:

- Asymptomatic fibroids 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.

Transcatheter embolization of uterine arteries as a treatment of postpartum uterine hemorrhage meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

One repeat transcatheter embolization of uterine arteries to treat uterine fibroids after an initial uterine artery embolization meets Blue Cross and Blue Shield of Alabama’s medical criteria for
coverage when there is documentation of continued symptoms such as bleeding or pain and there are persistent symptoms in combination with findings on imaging of an incomplete initial procedure, as evidenced by continued blood flow to the previously treated regions.

Transcatheter embolization does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational for the management of all other indications, including cervical ectopic pregnancy and uterine arteriovenous malformation.

Effective for dates of service on or after November 7, 2011 and prior to September 4, 2012:
Laparoscopic occlusion of the uterine arteries using bipolar coagulation does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Transcatheter embolization of uterine arteries as a treatment of uterine fibroids meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when:
- Asymptomatic fibroids 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 transcatheter embolization of uterine arteries to treat persistent symptoms of uterine fibroids after an initial uterine artery embolization does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Effective for dates of service on or after August 23, 2011 and prior to November 7, 2011:
Transcatheter embolization of uterine arteries as a treatment of uterine fibroids meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when:
- Asymptomatic fibroids 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 transcatheter embolization of uterine arteries to treat persistent symptoms of uterine fibroids after an initial uterine artery embolization does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.
Effective for dates of service July 24, 2002 through August 22, 2011:

Uterine artery embolization for the treatment of uterine fibroids (leiomyomata) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the following criteria are met:

1. Patient has symptoms that are confidently related to fibroids. The symptoms should be severe enough that surgical intervention, i.e., myomectomy or hysterectomy would be considered. These symptoms include:
   a) Menorrhagia—excessive menstrual bleeding. Menorrhagia is defined as menses of 80 mL or more. Normal menses volume is 30-40 mL, which corresponds to 10-15 pads or tampons moderately soaked. The bleeding must be refractory to medical treatment or the patient is not considered a candidate for medical therapy.
   b) Pelvic pain and/or pressure.
   c) Urinary symptoms related to compression of the bladder.
   d) Dyspareunia—difficult or painful sexual relations.
2. Iron deficiency or blood—low anemia which is felt to be due to vaginal bleeding and not responsive to iron therapy.
3. Endometrial pathology such as hyperplasia or cancer should be ruled out.
4. An imaging procedure such as ultrasound or MRI should be performed to verify symptoms are the result of myomata (uterine fibroid).

Uterine Artery Embolization does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of infertility or for a condition for which it is contraindicated.

Transcatheter uterine artery embolization to treat uterine fibroids is contraindicated for the following conditions:

1. Patient has symptoms that are suggestive of endometrial, cervical, or ovarian cancer, and the suspected cancer has not been ruled out.
2. Patient is pregnant.
3. Patient has chronic pelvic infection.
4. Patient has a history of prior pelvic irradiation.
5. Patient has a history or renal failure.
6. Patient is asymptomatic or mildly symptomatic of uterine fibroids.
7. Patient is experiencing menstrual symptoms or fibroid growth as a result of postmenopausal hormone replacement therapy.
8. Severe contrast medium allergy.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.
Key Points:
This policy is based in part on a 2002 TEC Assessment. The policy is regularly updated with searches of the MEDLINE database. The following is a summary of the key literature to date on uterine artery embolization (UAE).

UAE for treatment of uterine fibroids
Initial UAE procedure
A number of randomized controlled trials (RCTs) evaluating UAE for treatment of uterine fibroids have been published. In addition, there have been several systematic reviews of these RCTs. A 2012 Cochrane review included five 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 two years (odds ratio [OR]=0.69, 95% confidence interval [CI], 0.40 to 1.21, 5 trials) or five years (OR=0.90, 95% CI, 0.45 to 1.90, 2 trials). UAE was associated with a lower procedure length, shorter hospital stay, shorter time to resumption of routine activities, and lower likelihood of blood transfusion. There were no significant differences between UAE and surgery in terms of major complications, but there was a higher rate of minor complications and reintervention with UAE.

In 2011, van der Kooij et al published a meta-analysis of RCTs comparing UAE and surgery for treating symptomatic uterine fibroids and presented up to five-year follow-up data. The investigators identified 11 articles reporting on 5 RCTs. The overall intraprocedural and early postprocedural complication rates were similar with the two procedures. However, length of hospital stay, the need for blood transfusion, and febrile morbidity were significantly lower in the UAE group compared with the surgery group. At 12 months, a pooled analysis of two studies found a significantly higher reintervention rate in the UAE group compared with the surgery group (odds ratio [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 five years. The reintervention rate was significantly higher at five years, according to a pooled analysis of two trials (OR=5.41, 95% CI, 2.48 to 11.81).

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

Representative trials are described next.
The Randomized Trial of Embolization versus Surgical Treatment for Fibroids (REST) multicenter trial assigned patients in a 2:1 ratio to undergo UAE (n=106) or surgery (43 hysterectomies and eight myomectomies). The embolization group had lower postoperative pain (3.0 vs 4.6, respectively) and faster recovery (e.g., one- vs five-day median hospitalization, 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 of 157 (92%) randomized patients were included in the five-year analysis. Quality-of-life and symptom scores were similar in the two groups at five 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 five, markedly better). By the five-year follow-up, 27 of 106 (25%) in the UAE group and two 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 five-year period was 32% in the UAE group and 4% after surgery. In the UAE group, there were three technical failures of the procedure, eight repeat UAEs, and 18 hysterectomies. Note that one woman had both a repeat UAE and a hysterectomy, and two women were not embolized after randomization and subsequently underwent surgery.

The Embolization versus hysterectomy (EMMY) trial from the Netherlands included 177 women with uterine fibroids and heavy menstrual bleeding who were scheduled to undergo hysterectomy. They were randomized to receive UAE (n=88) or hysterectomy (n=89). By the two-year follow-up, 19 of the 81 (23%) women who actually received UAE had undergone a hysterectomy. An analysis of health-related quality-of-life outcomes at two years found similar improvement in both groups overall. The defecation distress inventory (DDI) score improved significantly in only the UAE group starting at six months. A report of five-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 analysis, 23 of 81 (28.4%) women who had received UAE underwent hysterectomy during the five years. Including the hysterectomies, 58 of 81 (71.6%) women in the UAE group no longer had menorrhagia. There were no significant differences between groups in health-related quality of life at five 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 five years (mean of 6.87) compared with two 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 five years and 5.80 at two years, p=0.34. There was also not a statistically significant difference in the rate of reported urinary incontinence. Similar to the two-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 five 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 (two vs four 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 one year. Nine patients (11%) in the UAE group required additional intervention, and three patients (4%) in the myomectomy group later underwent hysterectomy.

An RCT by Hald et al in Norway evaluated clinical outcomes in 66 premenopausal women (mean age, 43 years) with symptomatic uterine fibroids who were randomized to treatment with either laparoscopic occlusion of uterine arteries or UAE. 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 six 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 six 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 with the laparoscopy group (48%, n=17), p=0.02. Moreover, fewer patients in the UAE group (7%, n=2) had a hysterectomy than in the laparoscopy group (28%, n=8), p=0.41. The authors concluded that UAE is superior to laparoscopic 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 with surgery. Meta-analyses of RCTs have found similar levels of quality of life after five years among women receiving UAE or surgery, although there were more reinterventions in the UAE group.

Repeat UAE to treat recurrent or persistent symptoms

No RCTs focusing on repeat UAE were identified; there are published case series. In 2009, McLucas et al published a study in which the charts of 1058 women who had undergone initial bilateral UAE at several U.S. centers were reviewed. 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 six months postembolization. Before the second UAE procedure, 27 of the 34 (79%) women reported severe bleeding, and only two (6%) women reported severe bleeding after the procedure. Similarly, the number of women with severe pain decreased from 20 (59%) to two (6%), and with severe pressure decreased from 18 (53%) to 2 (6%). A total of four women experienced severe levels of one or more symptoms after the second UAE. Prospective comparative studies are needed to confirm the findings.

In 2006, Yousefi et al reported on 24 patients who underwent repeat embolization for recurrent or persistent symptoms six to 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.

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

As a recent example, a 2014 RCT by Shlansky-Goldberg et al randomized 60 women with symptomatic uterine fibroids to UAE using either Embosphere microspheres (n=30) or spherical PVA (n=30). The study was funded by the manufacturer of the spherical PVA product. The primary study outcome was complete or near-complete infarction of the dominant tumor (an infarction rate of at least 91%), as measured by magnetic resonance imaging 24 hours after UAE. The primary end point was achieved in 29 of 29 (100%) cases in the spherical PVA group and 28 of 30 (93%) cases in the Embosphere group; the difference between groups was not statistically significant. One patient was excluded from the analysis. Similarly, at three months, there was not a statistically significant difference in the rate of complete or near-complete infarction rates between groups.

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

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

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

In 2011, Ganguli et al published data on 66 women who underwent UAE for the treatment of postpartum hemorrhage. The clinical success rate, defined as obviation of hysterectomy, was 95%. Three of 66 (5%) women had a subsequent hysterectomy. In addition to the three clinical failures, there were three (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 endometritis. Nine pregnancies after UAE were identified; there were two spontaneous abortions and seven viable gestations.

In 2009, Kirby et al published a retrospective analysis of data from 43 women who underwent UAE for primary postpartum hemorrhage. In this study, clinical success was defined as cessation of bleeding without need for repeat embolization, laparotomy or hysterectomy and without mortality. Eight of 43 (19%) of women had a hysterectomy before UAE. Of the remaining 35 women, clinical success was achieved in 29 women (83%). Considering the sample as a whole, the clinical success rate was 29 of 43 (67%). Complications among women who had a UAE without a previous hysterectomy included 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.

**UAE for treatment of cervical ectopic pregnancy**

No RCTs or other comparative studies evaluating UAE for treating cervical ectopic pregnancy were identified. The published literature consisted of case series with small numbers of patients. Sample sizes ranged from two to 20 patients, and most studies had fewer than 10 patients. The largest prospective series was conducted in China by Xiaolin et al. Patients underwent UAE and in conjunction with methotrexate injections before, during, and after the UAE procedure. Median follow-up was 12 months (range, one 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 (b)-hCG. The uterus was preserved in all patients, and normal menses resumed after two to four months. Eight of 16 (50%) women who attempted another pregnancy achieved a normal pregnancy within 1 year. There were two miscarriages and six live births at term.
Section Summary
There is a lack of RCTs in UAE for treating cervical ectopic pregnancy and only a few small case series were available.

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

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

Impact of UAE treatment on fertility and pregnancy outcomes
Several systematic reviews have been published. In 2014, Doumouchtis et al identified 17 studies with a total of 675 participants reporting on fertility outcomes after UAE for postpartum hemorrhage. To be included in the review, studies needed to report on a minimum of five cases. None of the studies identified were RCTs. A total of 168 of the 675 patients (25%) wanted a pregnancy following UAE, and 126 of the 168 (75%) women who desired pregnancy achieved conception. There were a total of 136 term live births and 30 cases of pregnancy loss (ectopic pregnancy, miscarriage, elective abortion). Previously, in 2013, Mohan et al identified 21 studies reporting pregnancy outcomes and/or pregnancy complications after UAE for treatment of either postpartum hemorrhage or uterine fibroids. The authors reported that the cumulative pregnancy and miscarriage rates among women trying to conceive following UAE for uterine fibroids was 59% and 28%, respectively and the cumulative live birth rate was 65%. The term delivery rate was 61%. In the studies on UAE for postpartum hemorrhage, the cumulative pregnancy rate, based on a small number of pregnancies, was 87.2%. Rates of miscarriage and live births were not reported following UAE for postpartum hemorrhage. Most of the studies included in the systematic review were observational and had no or inadequate controls. There was only one RCT. This study, by Mara et al 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 six months after the procedure before they attempted pregnancy. At final follow-up, 13 of 26 women (50%) in the UAE group who tried to conceive became pregnant compared with 31 of 40 (76%) in the myomectomy group; the difference between groups was not statistically significant. Among women in the UAE group who became pregnant, the abortion rate was 64% and the delivery rate was 19%. In the myomectomy group, the abortion rate was 23%, and the delivery rate was 48%.
Section Summary
Reviews of fertility and pregnancy outcomes after UAE suggest that successful pregnancy is possible after UAE for treatment of uterine fibroids or postpartum hemorrhage. One review found higher rates of miscarriage and postpartum hemorrhage after UAE for treatment of uterine fibroids compared with treatment of fibroids with myomectomy. There are limited data on pregnancy outcomes in women who became pregnant following UAE for treatment of postpartum hemorrhage.

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

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

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

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

In 2013 ACOG reaffirmed a 2008 practice bulletin (No. 76) on management of postpartum hemorrhage. The bulletin states that UAE may be indicated under the following circumstances:
“A patient with stable vital signs and persistent bleeding, especially if the rate of loss is not excessive, may be a candidate for arterial embolization. Radiographic identification of bleeding vessels allows embolization with Gelfoam, coils, or glue. Balloon occlusion is also a technique used in such circumstances. Embolization can be used for bleeding that continues after hysterectomy or can be used as an alternative to hysterectomy to preserve fertility.”

**Key Words:**
Uterine artery embolization, fibroids, leiomyomata, UAE, TruFill PVA particles, Embosphere Microspheres, Contour Emboli PVA, Conture SETM, Cook Incorporated polyvinyl alcohol foam embolization particles, laparoscopic occlusion of the uterine arteries using bipolar coagulation, bipolar coagulation occlusion of uterine arteries, laparoscopic occlusion of uterine arteries

**Approved by Governing Bodies:**
Cordis Endovascular Systems, Inc. TruFill (polyvinyl alcohol particles) was cleared for marketing with 510(k) approval in 1997 for use as indicated; “TruFill PVA particles may be used for vascular occlusion of blood vessels within the neurovascular systems. They are intended for use in the endovascular management of arteriovenous malformations and neoplastic lesions when presurgical devascularization is desirable”. The use of the PVA particles for uterine artery embolization represents an off-label use of the FDA approved device.

In April 2000, Embosphere® Microspheres (Biosphere Medical) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for hypervascularized tumors and arteriovenous malformations.

In November 2002, this product was cleared for marketing specifically for use in uterine fibroid embolization. Since that time, several other devices have been cleared for marketing.

In 2003, Contour® Emboli PVA (Boston Scientific) was cleared for the embolization of peripheral hypervascular tumors and peripheral arteriovenous malformations.

In March 2004, the Contour SETM (Boston Scientific) was cleared by FDA for treatment of uterine fibroids.

In December 2008, Cook Incorporated Polyvinyl Alcohol Foam Embolization Particles received FDA marketing clearance for use in uterine fibroid embolization.

**Benefit Application:**
ITS Home: No special benefit rules apply.
ITS Host: Not subject to bundling edits.
FEP contracts: Special benefit consideration may apply. Refer to member’s benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.
**Current Coding:**

CPT code:  
**37242** Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (e.g., congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)  
*(Effective 01/01/2014)*

**37243** Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction  
*(Effective 01/01/2014)*

**37244** Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation  
*(Effective 01/01/2014)*

**Previous Coding:**

CPT code:  
**37210** Uterine fibroid embolization (UFE, embolization of the uterine arteries to treat uterine fibroids, leiomyomata), percutaneous approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the procedure  
*(Deleted effective 01/01/2014)*

**References:**

36. Moss JG, Cooper CG, Khaund A et al. Randomized comparison of uterine artery embolization (UAE) with surgical treatment in patients with symptomatic uterine fibroids (REST trial): 5-years results. BJOG 2011; 118(8):936-44.

Policy History:
Medical Review Committee, December 1999
Medical Policy Group, September 24, 2001
Medical Review Committee, July 2002
Medical Policy Group, August 2002
This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.