Name of Policy:
Occlusion of Uterine Arteries Using Transcatheter Embolization or Laparoscopic Occlusion to Treat Uterine Fibroids

Policy #: 022  Latest Review Date: August 2018
Category: Surgery/Radiology  Policy Grade: B

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 for 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, gel foam, coils or glue 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, bleeding uterine arteriovenous malformation and adenomyosis.

**Uterine Fibroids**

Uterine leiomyomata (i.e., 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 typically recommended when accompanied by menorrhagia, pelvic pain, or urinary symptoms (i.e., frequency), or when the fibroids 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 (the removal of fibroids with retention of the uterus) are recommended to maintain fertility. 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 which the fibroid is not physically removed; 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, 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, treatment of bleeding uterine arteriovenous malformation and treatment of adenomyosis.

**Ectopic Pregnancies**

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.

**Treatment**

First-line treatment for patients with minimal symptoms is systemic methotrexate. In patients with high β-human chorionic gonadotrophin, 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 Arteriovenous Malformations
Uterine AVMs are rare but may cause severe 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
Treatment options include hysterectomy, uterine artery ligation, and uterine artery embolization.

Adenomyosis
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
Treatment options include surgery and hormone therapy.

Uterine Artery Embolization
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 AVM, and adenomyosis.

Policy:
Effective for dates of service on and after November 6, 2016:
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 for the management of all other indications including cervical ectopic pregnancy, uterine arteriovenous malformation and adenomyosis does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Laparoscopic occlusion of the uterine arteries using bipolar coagulation or vascular clips 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 September 4, 2012 and prior to November 6, 2016:
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, uterine arteriovenous malformation.

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:
The policy has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through June 4, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Transcatheter Uterine Artery Embolization
Clinical Context and Test Purpose
The purpose of transcatheter uterine artery embolization (UAE) in patients who have uterine fibroids, postpartum uterine hemorrhage, cervical ectopic pregnancy, uterine arteriovenous malformation (AVM), or adenomyosis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does transcatheter UAE improve the net health outcomes in women with uterine fibroids, postpartum uterine hemorrhage, cervical ectopic pregnancy, AVM, or adenomyosis?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant populations of interest are:
- Women with uterine fibroids
- Women with uterine fibroids who have undergone prior UAE
- Women with postpartum uterine hemorrhage
- Women with cervical ectopic pregnancy
- Women with uterine AVM
• Women with adenomyosis.

Interventions
The intervention of interest is transcatheter UAE, which is a minimally invasive technique in which a catheter is used to inject small embolic agents into the uterine arteries and block blood supply. With the blood supply to uterine fibroids and the uterus blocked, the fibroids will shrink.

Comparators
The following therapies, most of which are more invasive, are currently being used to make decisions about uterine fibroids, postpartum uterine hemorrhage, cervical ectopic pregnancy, AVM, or adenomyosis:

• For women with uterine fibroids: hysterectomy, myomectomy, and other uterine fibroid treatments
• For women with uterine fibroids who underwent UAE: hysterectomy and myomectomy
• For women with postpartum uterine hemorrhage: hysterectomy or uterine-sparing surgery
• For women with cervical ectopic pregnancy: medication (e.g., methotrexate) or surgery
• For women with uterine AVM: medication or hysterectomy
• For women with adenomyosis: medication or hysterectomy.

Outcomes
The general outcomes of interest, by indication, include:

• For women with uterine fibroids, patient satisfaction (quality of life), live birth rates (when the comparison is a uterine-sparing procedure), uterine volume reduction, fibroid volume reduction, and reintervention rates
• For women with uterine fibroids who underwent UAE, symptom control
• For women with postpartum uterine hemorrhage, control of bleeding and live births
• For women with cervical ectopic pregnancy, clinical and technical success and recurrent bleeding
• For women with uterine AVM, symptom control and reintervention rates
• For women with adenomyosis, quality of life and symptom control.

Timing
Timing depends on the population and outcomes measured:

• For women with uterine fibroids, quality of life (in years); uterine and fibroid reduction (in months); live birth rates (years); reintervention rates (in years)
• For women with uterine fibroids who underwent UAE, symptom control (in months to years)
• For women with postpartum uterine hemorrhage, control of bleeding (postprocedure) and live births (in years)
• For women with cervical ectopic pregnancy, clinical and technical success (postprocedure) and recurrent bleeding (in months)
• For women with uterine AVM, symptom control (in months to years) and reintervention rates (months to years)
• For women with adenomyosis, quality of life (in months to years) and symptom control (in months to years).

Setting
Transcatheter UAE is administered in a tertiary care setting

**Uterine Fibroids**

Initial UAE Procedure for Uterine Fibroids
A number of randomized controlled trials (RCTs) evaluating UAE for treatment of uterine fibroids have been published. RCTs have compared UAE with hysterectomies, myomectomies, laparoscopic occlusion of uterine arteries, and focused ultrasound.

Systematic Reviews
A 2014 Cochrane review included 7 RCTs comparing UAE to other surgical interventions in women with symptomatic uterine fibroids. Four of the RCTs excluded women who desired pregnancy in the future. The comparison intervention was hysterectomy in 3 trials, hysterectomy or myomectomy in 2 trials, and myomectomy in 2 trials. The review’s 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 surgery 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). Only one study reported live birth rate so meta-analysis was not possible UAE was associated with a higher rate of minor complications at 1 year (OR: 1.99, 95% CI: 1.41 to 2.81, 6 trials) and there was not a 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 (OR: 0.07, 95% CI: 0.01 to 0.52, 2 trials). The rate of further surgical interventions within 2 years was significantly increased in the UAE group (OR: 3.72, 95% CI: 2.28 to 6.04, 6 trials).

A 2014 systematic analysis and meta-analysis by Das et al identified 10 studies comparing the efficacy of 1 embolic agent used in UAE to another intervention or comparing 2 embolic agents with one another. Five of the studies were RCTs and 5 were nonrandomized controlled trials. Embosphere microspheres were used in all of the RCTs. In a pooled analysis of data from 2 studies comparing Embosphere to spherical polyvinyl alcohol (PVA) for treatment of uterine fibroids, there was not a statistically significantly between-group difference in outcomes (uterine volume reduction and dominant fibroid volume reduction). Data from other studies were not pooled, but a qualitative analysis of study findings did not suggest that any agent was clearly superior or inferior to any other agent.

A 2013 systematic review by Martin et al focused on comparing complication 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 another 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 compared with surgery, but a wide CI indicating imprecision of the risk estimate (OR=6.04, 95% CI, 2.0 to 18.1).

Van der Kooij et al (2011) published a systematic review and meta-analysis of RCTs comparing UAE with surgery (hysterectomy or myomectomy) for treating symptomatic uterine fibroids and presenting up to 5 years 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). 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). Pooled analyses of quality of life (QOL) variables at 12 months found no significant differences between groups. Results were similar after five years.

Randomized Controlled Trials

**UAE vs Hysterectomy or Myomectomy**

The Randomized Trial of Embolization versus Surgical Treatment for Fibroids (REST) multicenter trial assigned patients in a 2:1 ratio to undergo UAE (n=106) or surgery (43 hysterectomies and 8 myomectomies). The embolization group had lower postoperative pain (3.0 vs 4.6, respectively) and faster recovery (e.g., 1-day vs 5-day median hospitalization, respectively). Of 7 identified pregnancies in the UAE group, 2 resulted in successful live births. Five-year follow-up data from the REST trial were published in 2011. A total of 144 of 157 (92%) randomized patients were included in the 5-year analysis. Quality-of-life and symptom scores were similar in the 2 groups at 5 years. For example, the mean symptom score was 4.5 in the UAE group and 4.8 in the surgery group (scores ranged from 15, markedly worse to 5, markedly better). By the 5-year follow-up, 27 of 106 (25%) in the UAE group and 2 of 51 (4%) in the surgery group had received an additional intervention for continued or recurrent symptoms. The total rate of further intervention for symptoms or adverse events over the 5-year period was 32% in the UAE group and 4% after surgery. In the UAE group, there were 3 technical failures of the procedure, 8 repeat UAEs, and 18 hysterectomies. Note that 1 woman had both a repeat UAE and a hysterectomy, and 2 women were not embolized after randomization and subsequently underwent surgery.

The EMbolization versus hysterectomy (EMMY) trial from the Netherlands included 177 women with uterine fibroids and heavy menstrual bleeding who were scheduled to undergo hysterectomy. They were randomized to receive UAE (n=88) or hysterectomy (n=89). By the 2-year follow-up, 19 (23%) of the 81 women who actually received UAE had undergone a hysterectomy. An analysis of health-related quality-of-life outcomes at 2 years found similar improvement in both groups overall. The defecation distress inventory (DDI) score improved significantly in only the UAE group starting at 6 months. A report of 5-year outcome data from the EMMY trial was published in 2010. At 5 years 70 (79%) of the 89 patients originally
randomized to the hysterectomy group and 75 (85%) of 88 in the UAE group completed questionnaires. In an intention-to-treat analysis, 23 (28.4%) of 81 women who had received UAE underwent hysterectomy during the 5 years. Including patients who had subsequent hysterectomies, 58 (71.6%) of 81 women in the UAE group no longer had menorrhagia. There were no significant differences between groups in health-related quality of life at 5 years, as assessed by mental and physical components of the 36-Item Short-Form Health Survey (SF-36). Ten-year outcomes were reported by de Brujin 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 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 than surgery (2 days vs 4 days, respectively; p<0.0001). There were no significant differences in minor or major complications. A total of 120 (74%) of 163 were available for the analysis of quality of life, the primary outcome measure. There were no significant differences between groups in change in quality-of-life scores from baseline to 1 year. Nine patients (11%) in the UAE group required additional intervention (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 in Norway evaluated clinical outcomes in 66 premenopausal women (mean age, 43 years) with symptomatic uterine fibroids who were randomized to treatment with either laparoscopic occlusion of uterine arteries or UAE. Women who wanted to bear children in the future, had a large uterus, had undergone multiple previous open abdominal surgeries, and who had bleeding disorders were excluded. The primary outcome was reduction in blood loss at 6 months’ postintervention, as measured by a pictorial blood loss assessment chart. Fifty-eight women underwent treatment, 29 with UAE and 29 with laparoscopic occlusion. The proportion of women who had a reduction in blood loss after 6 months did not differ between the treatment groups (52% after UAE and 53% after laparoscopy, respectively; p=0.96). An additional publication reported on follow-up data at a median of 48 months after treatment (range, 8-73 months). The cumulative clinical failure and recurrence rate was significantly lower for patients in the UAE group (17%, n=5) compared with the laparoscopy group (48%, n=17), p=0.02. Moreover, fewer patients in the UAE group (7%, n=2) had a hysterectomy than in the laparoscopy group (28%, n=8), p=0.41. The authors concluded that UAE is superior to laparoscopic occlusion of uterine arteries for treatment of uterine fibroids.

**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.

Section Summary: Initial UAE 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 or 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 is needed. The available evidence from RCTs does not suggest that any one embolization agent is clearly superior to any other agent.

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 6 months postembolization. Before the second UAE procedure, 27 of the 34 (79%) women reported severe bleeding, and only 2 (6%) women reported severe bleeding after the procedure. Similarly, the number of women with severe pain decreased from 20 (59%) to 2 (6%), and with severe pressure decreased from 18 (53%) to 2 (6%). A total of 4 women experienced severe levels of 1 or more symptoms after the second UAE.

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

Pregnancy Outcomes with Uterine Fibroids
Mara et al (2008) conducted a controlled trial that randomized 121 women with uterine fibroids who desired future pregnancies to UAE or myomectomy. Participants were followed-up for a mean of 25 months; they were advised to wait for at least 6 months after the procedure before they attempted pregnancy. At final follow-up, 13 (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: Repeat UAE Procedures for Recurrent or Persistent Uterine Fibroid Symptoms
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.

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 have been published.

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 literature on second-line treatment of postpartum hemorrhage. The success rate of arterial embolization for postpartum hemorrhage reported in uncontrolled studies ranged from 70% to 100%, and from 60% to 83% in placenta accreta.

Case Series
Among the representative, larger case series is the retrospective evaluation by Kim et al (2013) who analyzed 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 three clinical failures, there were 3 (5%) major complications after UAE: 1 case of lower extremity deep vein thrombosis, 1 case of postprocedural pancreatitis, and 1 admission for intravenous antibiotic treatment for presumed endometritis. Nine pregnancies after UAE were identified; there were 2 spontaneous abortions and 7 viable gestations.

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

Pregnancy Outcomes With Postpartum Hemorrhage
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 5 cases. None of the studies identified were RCTs. A total of 168 of the 675 patients (25%) wanted a pregnancy following UAE, and 126 of the 168 (75%) women who desired pregnancy achieved conception. There were a total of 136 term live births and 30 cases of pregnancy loss (ectopic pregnancy, miscarriage, elective abortion).

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. Most studies included in the systematic review were observational and had no or inadequate controls. 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.

Section Summary: Postpartum Uterine Hemorrhage
There is a lack of RCTs or other controlled studies on UAE for treatment of postpartum hemorrhage. Case series have been conducted with over 1400 patients and have shown a high rate of successfully stopping 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.

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 with small numbers of patients. 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 underwent UAE and in conjunction with methotrexate injections before, during, and after the UAE procedure. Median follow-up was 12 months (range, 1 to 50 months). Two (10%) of 20 patients had recurrent vaginal bleeding; the other 18 had no significant bleeding after UAE. Five patients (25%) had an additional curettage procedure due to bleeding and/or high levels of beta (b)-hCG. The uterus was preserved in all patients, and normal menses resumed after 2 to 4 months. Eight (50%) of 16 women who attempted another pregnancy achieved a normal pregnancy within 1 year. There were 2 miscarriages and 6 live births at term.

Section Summary: UAE for Treatment of 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, 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.

Uterine Arteriovenous Malformation
No RCTs or other comparative studies evaluating UAE for treating uterine arteriovenous malformation (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, 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: UAE for Treatment of Uterine AVMs
The limited noncomparative evidence is insufficient to determine the effect of UAE on health outcomes in patients with bleeding associated with uterine arteriovenous malformations. Additional data, ideally controlled trials comparing UAE to alternative uterine-sparing treatments, are needed to determine the safety and efficacy of UAE for treating uterine AVMs.

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

Systematic Reviews
A 2011 systematic review of publications from 1999 through 2010 by Popovic et al evaluated literature on UAE for patients with adenomyosis, alone or in conjunction with uterine fibroids. The authors 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). 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 were published after 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 successfully underwent bilateral UAE and were included in the analysis. At 12 months, patients were queried about change in dysmenorrhea symptoms. Thirteen patients (11.3%) reported slight symptom improvement, 64 (55.7%) reported moderate improvement, and 31 (27.0%) reported marked improvement. Seven (6%) patients reported no change in symptoms.

In 2015, Bae et al retrospectively reviewed outcomes in 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 and the remainder reported only 1 of these 2 symptoms. The extent of necrosis of adenomyosis 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% necrosis, 58% were symptom-free at 18 months; among 40 patients with greater than 34% necrosis, 94% were symptom-free at 18 months.

Section Summary: Adenomyosis
There is a lack of RCTs or other controlled comparative studies on UAE for 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.

Laparoscopic Occlusion of Uterine Arteries
Helal et al (2010) compared the effectiveness and safety of UAE vs laparoscopic occlusion to treat symptomatic fibroids in 90 premenopausal women. The primary outcome was patient satisfaction regarding menstrual blood loss as compared to before the procedure. The patients were followed for 12 months. After 6 months of follow up, significantly more participants reported heavy or very heavy bleeding in the LUAO group. After 12 months of follow up, there was no significant difference between the groups. To conclude, the authors state “to perform successful laparoscopic uterine artery occlusion, the surgeon has to be equipped with the necessary laparoscopic skills and should be able to precisely locate the uterine artery to correctly ligate the vessels. If these prerequisites are not met, massive bleeding may ensure necessitating
laparotomy; therefore, the laparoscopic procedure for leiomyoma treatment should be confined to centers with appropriate expertise in laparoscopic surgery.

Mara et al (2012) published a prospective, nonrandomized study that compared UAE and laparoscopic uterine artery occlusion (LUOA) in 100 patients. All patients were not surgical candidates for laparoscopic myomectomy. At the 6 month follow up, mean shrinkage of fibroid volume was 53% in the UAE group and 39% in the LUAO group. Also of note, 82% of women had complete myoma infarction in the UAE group versus only 23% in the LUAO group. In this study, the UAE group had more complications than the LUAO group. The authors conclude by stating that “UAE is more effective in causing complete ischemia of fibroids, but it is associated with a greater risk of intrauterine necrosis. Both methods have low rate of serious complications (except for a high abortion rate).”

Panagiotopoulou et al (2014) published a systematic review and indirect treatment comparison meta-analysis to evaluate the effectiveness of uterine sparing interventions in women with symptomatic fibroids. There were 5 trials included in the review with 436 women involved. According to the authors, indirect treatment comparison showed that myomectomy and UAE resulted in higher rates of patient satisfaction and lower rates of clinical failure than LUAO. There was no difference between the myomectomy, UAE, and LUAO groups in terms of ovarian failure and complication rates. The authors conclude by stating that “LUAO is less effective than UAE and myomectomy in the treatment of symptomatic fibroids.”

Dubuisson et al (2015) published a literature review to define the role of preventive UAO during laparoscopic myomectomy. The authors reviewed 9 non-randomized case control studies and 2 RCTs. They state that the “main purpose of facilitating the operative procedure by reducing blood loss has not been clearly demonstrated in randomized trials. Observational comparative studies found an improvement in the effectiveness of treatment, both on clinical symptoms and on the recurrence of leiomyomas. Finally, there are few data examining the effect of uterine artery occlusion on later fertility in female patients of childbearing age, which limits its current use.” They go on to state that additional RCTs are needed to better define the role of LUAO, especially for women who desire to preserve fertility.

Section Summary: Laparoscopic Occlusion of Uterine Arteries
There is minimal published literature regarding laparoscopic occlusion of the uterine arteries. The published literature mainly consists of case series. Additional data from controlled trials are needed to permit conclusions regarding the technology; therefore, it is considered investigational.

Summary of Evidence
For individuals who have uterine fibroids who receive transcatheter UAE, the evidence includes randomized controlled trials (RCTs) 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have persistent uterine fibroids despite uterine artery embolization treatment 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, there is evidence from RCTs 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 qualitatively 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 with over 1400 women found a rate of success of stopping bleeding that ranged from 58% to 98%. Postpartum uterine hemorrhage is an emergency situation with serious potential consequences (i.e., maternal mortality). Conducting RCTs 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

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 to medication or surgery, are needed to draw conclusions about 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 (AVM) 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 AVM treated with UAE. Additional controlled studies comparing UAE hysterectomy are needed to conclude the safety and efficacy of UAE in patients with uterine arteriovenous malformation. 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 and may 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 to 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.

For individuals who have uterine fibroids and have laparoscopic uterine artery occlusion, the evidence consists of metaanalysis and nonrandomized controlled trials. Relevant outcomes are patient satisfaction, re-intervention rates, and complication rates. The evidence has shown that LUAO patient satisfaction scores are lower compared to UAE and that this procedure is less effective than UAE and myomectomy. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Practice Guidelines and Position Statements**

**American College of Obstetricians and Gynecologists**
In 2014, 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.”

In 2013, ACOG issued a committee opinion on the management of acute abnormal uterine bleeding in non-pregnant reproductive aged women. This opinion was reaffirmed in 2017. The committee listed UAE among the surgical options for acute abnormal uterine bleeding and stated that the need for surgical treatment, including UAE, is based on the clinical stability of the patient, the severity of bleeding, contraindications to medical management, the patient’s lack of response to medical management, and the underlying medical condition of the patient.

ACOG (2017) published a practice bulletin (No. 183) on postpartum hemorrhage. UAE was recommended when less invasive techniques (uterotonic agents, uterine massage, uterine compression, manual removal of clots) failed. Studies have shown that the median success rate is 89% (range, 58%- 98%).

**Society of Obstetricians and Gynecologists of Canada**
In 2015, the Society of Obstetricians and Gynecologists of Canada published a clinical practice guideline on management of uterine leiomyomas. The guideline stated, “Of the conservative interventional treatments currently available, uterine artery embolization has the longest track record and has been shown to be effective in properly selected patients.”

The guidelines do not specifically address laparoscopic uterine artery occlusion as a stand-alone treatment. They do state that “Another option is to perform UAO by laparoscopy at the time of myomectomy, although the benefit seems controversial.”

**Society of Interventional Radiology**
The 2010 (reviewed and unchanged in 2014), 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.

American College of Radiology
The American College of Radiology (2018) published appropriateness criteria on the radiologic management of uterine fibroids. The College provided 6 scenarios when the use of transcatheter UAE presents a favorable risk-benefit ratio for patients and can be considered “usually appropriate”. Two of the scenarios involved child-bearing aged women with fibroids, one in which the woman did not want a hysterectomy and one in which the woman would keep her fertility options open. Four of the scenarios involved middle-aged women with fibroids accompanied by urinary frequency or bloating, diffuse adenomyosis, pelvic discomfort, and constipation.

U.S. Preventive Services Task Force Recommendations
Not applicable

Key Words:
Uterine artery embolization, fibroids, leiomyomata, UAE, TruFill PVA particles, Embosphere Microspheres, Contour Emboli PVA, Conture SÉ™, 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, adenomyosis

Approved by Governing Bodies:
In April 2000, Embosphere® Microspheres (Merit Medical, formerly 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 SÉ™ (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. In 2016, Bead Block™ microspheres (Biocompatibles UK) were cleared for marketing by FDA for embolization of uterine fibroids and AVMs.

Benefit Application:
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.
ITS Home: No special benefit rules apply.
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:

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

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

**References:**


49. McLucas B and Adler L. Uterine fibroid embolization compared with myomectomy. Inter J Gynecol Obstet 2001; 74(3); 297-299.


Policy History:
Medical Review Committee, December 1999
Medical Policy Group, September 24, 2001
Medical Review Committee, July 2002
Medical Policy Group, August 2002
Medical Policy Administration Committee, September 2002
Available for comment September 18-November 1, 2002
Medical Policy Group, July 2006 (1)
Medical Policy Group, February 2007 (3)
Medical Policy Group, February 2009 (1)
Medical Policy Panel, February 2011
Medical Policy Group, June 2011 (2): Title, Policy, Key Points, Key Words, References updated
Medical Policy Administration Committee, July 2011
Available for comment July 6 through August 22, 2011
Medical Policy Group, September 2011 (2): Policy and reference updated
Medical Policy Administration Committee, September 2011
Available for comment September 22 through November 7, 2011
Medical Policy Panel, July 2012
Medical Policy Group, July 2012 (2): Policy statement updated to cover UAE as treatment of postpartum uterine hemorrhage, one repeat UAE for uterine fibroids, and to not cover UAE for management of cervical ectopic pregnancy. Key Points, References, Key Words, Approved by Governing Bodies, References updated to support policy changes.
Medical Policy Administration Committee, July 2012
Available for comment July 26 through September 4, 2012
Medical Policy Panel, July 2013
Medical Policy Group, July 2013 (2): 2013 Update to Key Points and References; no change in policy statement
Medical Policy Group, December 2013 (3) 2014 Coding Update – added new codes 37242, 37243, and 37244 to current coding (effective 01/01/2014); moved code 37210 to previous coding (deleted effective 01/01/2014)
Medical Policy Panel, July 2014
Medical Policy Group, July 2014 (1): Update to Descriptions, Key Points and References; no change to policy statement.
Medical Policy Group, July 2014
Medical Policy Panel, July 2014 (4): Updates to Key Points, Approved Governing Bodies and References. Removed code 37242 from current coding and entered under previous coding. No change to policy statement.
Medical Policy Panel, August 2016
Medical Policy Administrative Committee, September 2016
Available for Comment September 21 through November 5, 2016
Medical Policy Panel, August 2017
Medical Policy Group, September 2017 (4): Updates to Description, Key Points, and References. “Vascular clips” was added to the policy statement regarding LUAO.
Medical Policy Panel, August 2018
Medical Policy Group, August 2018 (4): Updates to Description, Key Points, Approved by Governing Bodies and References. Also, deleted “Previous Coding Section”- CPT 37210 and 37242, deleted effective 01/01/2014. No change in Policy Statement.

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.