

# Protocol

## Occlusion of Uterine Arteries Using Transcatheter Embolization

(40111)

<b>Medical Benefit</b>		<b>Effective Date:</b> 01/01/15	<b>Next Review Date:</b> 09/19
<b>Preauthorization</b>	No	<b>Review Dates:</b> 01/07, 03/08, 03/09, 03/10, 03/11, 03/12, 09/12, 09/13, 09/14, 09/15, 09/16, 09/17, 09/18	

### **Preauthorization is not required.**

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: • With uterine fibroids	Interventions of interest are: • Transcatheter uterine artery embolization	Comparators of interest are: • Hysterectomy • Myomectomy • Other uterine fibroid	Relevant outcomes include: • Symptoms • Quality of life • Treatment-related morbidity
Individuals: • With persistent uterine fibroids despite prior uterine artery embolization	Interventions of interest are: • Repeat transcatheter uterine artery embolization	Comparators of interest are: • Hysterectomy • Myomectomy	Relevant outcomes include: • Symptoms • Quality of life • Treatment-related morbidity
Individuals: • With postpartum uterine hemorrhage	Interventions of interest are: • Transcatheter uterine artery embolization	Comparators of interest are: • Hysterectomy • Uterine-sparing surgery	Relevant outcomes include: • Overall survival • Symptoms • Treatment-related morbidity
Individuals: • With cervical ectopic pregnancy	Interventions of interest are: • Transcatheter uterine artery embolization	Comparators of interest are: • Medication (e.g., methotrexate)	Relevant outcomes include: • Treatment-related morbidity
Individuals: • With uterine arteriovenous malformation	Interventions of interest are: • Transcatheter uterine artery embolization	Comparators of interest are: • Medication • Hysterectomy	Relevant outcomes include: • Symptoms • Treatment-related morbidity
Individuals: • With adenomyosis	Interventions of interest are: • Transcatheter uterine artery embolization	Comparators of interest are: • Medication • Hysterectomy	Relevant outcomes include: • Symptoms • Treatment-related morbidity

### **DESCRIPTION**

Transcatheter uterine artery embolization (UAE) is a minimally invasive technique that involves the injection of small particles, gelfoam, coils, or glue into the uterine arteries to block the blood supply to the uterus and uter-

ine fibroids. It potentially serves as an alternative to hysterectomy. UAE has also been used to treat postpartum hemorrhage, cervical ectopic pregnancy, uterine arteriovenous malformations, and adenomyosis.

## 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 that the technology results in a meaningful improvement in the net health outcome.

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

For individuals who have postpartum uterine hemorrhage who receive transcatheter UAE, the evidence includes case series and a systematic review. Relevant outcomes are overall survival, symptoms, and treatment-related morbidity. The systematic review of case series assessing over 1400 women reported success rates of bleeding cessation 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. The evidence is sufficient to determine 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 with medication or surgery, are needed to assess the safety and efficacy of UAE in patients with cervical ectopic pregnancy. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

For individuals who have adenomyosis who receive transcatheter UAE, the evidence includes case series and a systematic review. Relevant outcomes are symptoms, and treatment-related morbidity. A systematic review of case series data found short-term improvement in 83% of patients and long-term improvement in 65% of patients, suggesting possible recurrence of symptoms over time. All studies were case series, which might have been subject to selection and/or observational biases. Additional case series published after the review have

reported that patients with greater necrosis of adenomyosis and patients with higher vascularity of lesions may experience higher response rates to UAE. Controlled studies comparing UAE with medication or surgery and reporting long-term symptom recurrence rates are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

## POLICY

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

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

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

## POLICY GUIDELINES

### PATIENT SELECTION CRITERIA

#### Initial procedure

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

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

#### Repeat procedure

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

## BACKGROUND

### 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 they are accompanied by menorrhagia, pelvic pain, 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 that 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, uterine artery embolization, involves selective catheterization of the uterine arteries with an injection of embolization material. Uterine artery embolization has also been used to control bleeding in situations such as severe postpartum hemorrhage, cervical ectopic pregnancy, bleeding uterine arteriovenous malformation (AVM), and adenomyosis.

## ECTOPIC PREGNANCIES

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  $\beta$ 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 MALFORMATION

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

## Treatment

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 situa-

tions such as severe postpartum hemorrhage, cervical ectopic pregnancy, bleeding uterine AVM, and adenomyosis.

## REGULATORY STATUS

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 AVMs. In 2002, this product was cleared for marketing specifically for use in uterine fibroid embolization. Since then, several other devices have been cleared for marketing. In 2003, Contour® Emboli PVA (Boston Scientific) was cleared for marketing by the FDA through the 510(k) process for the embolization of peripheral hypervascular tumors and peripheral AVMs. In March 2004, the Contour SE™ (Boston Scientific) was cleared for marketing by the FDA through the 510(k) process for treatment of uterine fibroid embolization. In December 2008, Polyvinyl Alcohol Foam Embolization Particles (Cook Inc.) was cleared for marketing by the FDA through the 510(k) process for use in uterine fibroid embolization. In 2016, Bead Block™ microspheres (Biocompatibles UK) were cleared for marketing by the FDA for embolization of uterine fibroids and AVMs. FDA product code: NAJ.

## RELATED PROTOCOL

Magnetic Resonance Guided Focused Ultrasound

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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