

FEP Medical Policy Manual

FEP 4.01.11 Occlusion of Uterine Arteries Using Transcatheter Embolization

Effective Policy Date: January 1, 2020

Original Policy Date: December 2011

Related Policies:

4.01.19 - Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids 7.01.109 - Magnetic Resonance Imaging–Guided Focused Ultrasound

Occlusion of Uterine Arteries Using Transcatheter Embolization

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 uterine 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.

OBJECTIVE

The objective of this evidence review is to determine whether the use of transcatheter uterine artery embolization improves the net health outcome in patients with uterine fibroids, postpartum uterine hemorrhage, cervical ectopic pregnancy, uterine arteriovenous malformation, and adenomyosis.

POLICY STATEMENT

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 section).

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 8 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 a urinary frequency not due to urinary tract infection.

Repeat Procedure

One repeat uterine artery embolization 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.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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 the treatment of uterine fibroids. In 2008, Polyvinyl Alcohol Foam Embolization Particles (Cook Inc.) was cleared for marketing by the FDA through the 510(k) process for the treatment of uterine fibroids. In 2008, Polyvinyl Alcohol Foam Embolization. In 2016, Bead Block[™] microspheres (Biocompatibles UK) were cleared for marketing by FDA for embolization of uterine fibroids and AVMs. FDA product code: NAJ.

RATIONALE

Summary of Evidence

For individuals who have uterine fibroids who receive transcatheter uterine artery embolization (UAE), the evidence includes randomized controlled trials (RCTs) and systematic reviews. The relevant outcomes are symptoms, quality of life (QOL), and treatment-related morbidity. The majority of studies have compared UAE with hysterectomy and myomectomy and found similar levels of symptoms and QOL 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 UAE who receive repeat transcatheter UAE, the evidence includes case series. The relevant outcomes are symptoms, QOL, 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. The 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 (ie, 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. The 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 (AVMs) who receive transcatheter UAE, the evidence includes case reports, case series, and a systematic review. The 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 AVMs treated with UAE. Additional controlled studies comparing UAE with hysterectomy are needed to assess the safety and efficacy of UAE in patients with uterine AVMs. 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. The 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 has 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Obstetricians and Gynecologists

The ACOG (2014) reaffirmed its 2008 practice bulletin on alternatives to hysterectomy in the management of leiomyomas.³⁷. This Bulletin (No. 96) contained the following statement on 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 ACOG (2013) issued a committee opinion on the management of acute abnormal uterine bleeding in nonpregnant reproductiveaged women.^{38,} This opinion was reaffirmed in 2017. The ACOG 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.

The ACOG (2017) published a practice bulletin (No. 183) on a postpartum hemorrhage.^{39,} 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 Interventional Radiology

The quality improvement guidelines from the Society of Interventional Radiology (2010;reviewed and unchanged in 2014) stated that UAE is indicated in women with uterine leiomyomas causing significant symptoms.⁴⁰, Absolute contraindications to UAE included a 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 was deemed a relative contraindication.

American College of Radiology

The American College of Radiology (2018) published appropriateness criteria on the radiologic management of uterine fibroids.^{41,} The College provided six 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.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
December 2012	Replace policy	Policy updated with literature review and references. Postpartum uterine hemorrhage added to medically necessary statement. Investigational statement added on UAE for management cervical ectopic pregnancy. Statement on repeat UAE changed to state that one repeat procedure may be considered medically necessary; patient selection information added to Policy Guidelines.
September 2013	Replace policy	Policy updated with literature review, References 4,14,18,19 and 22 added. Other references reordered or removed. No change to policy statements.
September 2014	Replace policy	Policy updated with literature review. Uterine arteriovenous malformation added to investigational policy statement. References 15-17 and 21-22 added.
September 2015	Replace policy	Policy updated with literature review; references 2 and 31-32 added. Policy statements unchanged.
September 2016	Replace policy	Policy updated with literature review; references 11, 17, 26, and 28-30 added. Adenomyosis added to investigational policy statement.
December 2018	Replace policy	Policy updated with literature review through June 4, 2018; references 15, 26-27, 30, 33- 34, 39 and 42 added. Policy statements unchanged.
December 2019	Replace policy	Policy updated with literature review through June 10, 2019; no references added. Policy statements unchanged.