BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

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

Policy #: 022
Category: Surgery/Radiology

Latest Review Date: August 2020
Policy Grade: **Effective September 21, 2020: Active policy but no longer scheduled for regular literature reviews and updates.**

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

Proprietary Information of Blue Cross and Blue Shield of Alabama
An Independent Licensee of the Blue Cross and Blue Shield Association

POLICY:

Effective for dates of service on and after November 6, 2016:

Blue Advantage will treat transcatheter embolization of uterine arteries as a treatment of uterine fibroids as a covered benefit 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.

Blue Advantage will treat transcatheter embolization of uterine arteries as a treatment of postpartum uterine hemorrhage as a covered benefit.

Blue Advantage will treat one repeat transcatheter embolization of uterine arteries to treat uterine fibroids after an initial uterine artery embolization as a covered benefit 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.

Blue Advantage will treat transcatheter embolization as a non-covered benefit and as investigational for the management of all other indications, including cervical ectopic pregnancy, uterine arteriovenous malformation and adenomyosis.

Blue Advantage will treat laparoscopic occlusion of the uterine arteries using bipolar coagulation or vascular clips as a noncovered benefit and as investigational.

Blue Advantage 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 Advantage administers benefits based on the members' contract and 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.

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 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 arteriovenous malformations (AVMs), and adenomyosis.

Laparoscopic occlusion of uterine arteries is a procedure that uses vascular clips or bipolar coagulation to cut off the blood supply to fibroids. The lack of blood causes the fibroids to die.

KEY POINTS:

The policy has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through June 26, 2020.

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 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 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 RCTs, case series and a systematic reviews. Relevant outcomes are overall survival, symptoms, and treatment-related morbidity. The systematic review of multiple RCTs and comparative observational studies of 1142 women found similar hemostatic effective rates for UAE and hysterectomy and found several benefits of UAE including reduced blood loss, operating time, and length of stay. The systematic review of case series assessing over 1400 women reported success rates of bleeding cessation that ranged from 58% to 98%. 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 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 (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 37243 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 (No. 557) 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.

In 2017, the ACOG 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 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 SE™, 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, Bead Block, Hydropearl

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 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 and a sampling of those are listed herein. 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 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. In 2020, Hydropearl® Microspheres (MicroVention, Inc.) was cleared for marketing by FDA for the embolization of arteriovenous malformations and hypervascular tumors, including uterine fibroids.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

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

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POLICY HISTORY:

Adopted for Blue Advantage, March 2005
Available for comment May 1-June 14, 2005
Medical Policy Group, July 2006
Medical Policy Group, February 2007
Medical Policy Group, February 2009
Medical Policy Group, June 2011
Medical Policy Group, September 2011
Available for comment September 22 through November 7, 2011
Medical Policy Group, July 2012
Available for comment July 26 through September 4, 2012
Medical Policy Group, December 2013
Medical Policy Group, July 2014
Medical Policy Group, July 2015
Medical Policy Group, September 2016
Available for Comment September 21 through November 5, 2016
Medical Policy Group, September 2017

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.
Medical Policy Group, September 2019
Medical Policy Group, August 2020.
Medical Policy Group, September 2020: Policy retired effective 9/21/2020. No longer scheduled for regular literature reviews and updates

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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.