



Louisiana

Occlusion of Uterine Arteries Using Transcatheter Embolization

Policy # 00130

Original Effective Date: 03/25/2002

Current Effective Date: 03/09/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Magnetic Resonance –Guided Focused Ultrasound is addressed separately in medical policy 00180.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Initial Procedure

Based on review of available data, the Company may consider transcatheter embolization of uterine arteries as a treatment of uterine fibroids or as a treatment of postpartum uterine hemorrhage to be **eligible for coverage.****

Patient Selection Criteria

The use of transcatheter embolization of uterine arteries as a treatment of uterine fibroids or as a treatment of postpartum uterine hemorrhage may be considered for coverage when ONE of the following criteria is met:

- Asymptomatic fibroid 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.

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Repeat Procedure

Based on review of available data, the Company may consider one repeat transcatheter embolization of uterine arteries to treat persistent symptoms of uterine fibroids after an initial uterine artery embolization (UAE) to be **eligible for coverage**.**

Note: 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 suggest a high rate of success following repeat procedures for this purpose, with the majority of patients reporting relief of symptoms.

When Services Are Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of transcatheter embolization of uterine arteries as a treatment of uterine fibroids when patient selection criteria are not met to be **investigational**.*

Based on review of available data, the Company considers transcatheter embolization for the management of all other indications, including cervical ectopic pregnancy, uterine arteriovenous malformation, and adenomyosis to be **investigational**.*

Background/Overview

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.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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 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. FDA product code: NAJ.

Rationale/Source

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.

For individuals who have uterine fibroids who receive transcatheter UAE, the evidence includes randomized controlled trials and systematic reviews. The 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.

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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, 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 randomized controlled trials 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 randomized controlled trials 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 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 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.

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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

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 3 physician specialty societies and 2 academic medical centers while this policy was under review in 2012. There was a consensus that uterine artery embolization (UAE) is medically necessary for treating uterine fibroids and near-consensus agreement that UAE is medically necessary for treating postpartum hemorrhage, particularly for the indications stated in the American College of Obstetricians and Gynecologists Practice Bulletin No. 76. Clinical input was mixed on repeat UAE and UAE for managing the cervical ectopic pregnancy. One reviewer who disagreed that repeat UAE is investigational provided detailed input on clinical situations in which a repeat procedure might be appropriate.

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. 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."

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The ACOG (2013) issued a committee opinion on the management of acute abnormal uterine bleeding in nonpregnant reproductive-aged women. 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. 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. 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.

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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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02942537	Single Blinded Randomized Study of Volume Reduction of Uterine Fibroids after Uterine Artery Embolization versus Computer Tomography or Ultrasound Guided Percutaneous Microwave Ablation Evaluated by Magnetic Resonance Imaging	36	Feb 2020
NCT02260752	Comparing Options in Management: Patient-Centered Results for Uterine Fibroids	3,094	Apr 2020
NCT01563783 ^a	The TRUST (Treatment Results of Uterine Sparing Technologies) Study	260	Dec 2022

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NCT02163525 ^a	The TRUST (Treatment Results of Uterine Sparing Technologies) U.S.A. Study	114	Jun 2024
<i>Unpublished</i>			
NCT02819609 ^a	Comparing Patient-Centered Outcomes after Treatment for Uterine Fibroids	12,234	Jan 2015 (completed)
NCT02884960 ^a	Safety and Efficacy of Embozene® Microspheres for Uterine Fibroid Embolization Compared to Embosphere® Microspheres for Symptomatic Relief from Uterine Fibroids	118	Oct 2018

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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| 04/15/2003 | Medical Policy Committee review |
| 05/12/2003 | Managed Care Advisory Council approval |
| 05/04/2004 | Medical Director review |
| 05/18/2004 | Medical Policy Committee review. Format revision. Clinical criteria revision. |
| 06/28/2004 | Managed Care Advisory Council approval |
| 06/07/2005 | Medical Director review |
| 06/21/2005 | Medical Policy Committee review. Format revision. Patient selection criteria added. Clinical criteria revision to include laparoscopic closure of uterine arteries. Policy title changed from, "Transcatheter Uterine Artery Embolization" to "Occlusion of Uterine Arteries Using Transcatheter Embolization or Laparoscopic Occlusion to Treat Uterine Fibroids". |
| 07/15/2005 | Managed Care Advisory Council approval |
| 07/07/2006 | Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged. |
| 09/06/2006 | Medical Director review |
| 09/20/2006 | Medical Policy Committee approval. No change to policy guidelines. |
| 11/07/2007 | Medical Director review |
| 11/15/2007 | Medical Policy Committee approval. No change to policy guidelines. |

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11/18/2009	Medical Policy Implementation Committee approval. No change to coverage eligibility.
11/04/2010	Medical Policy Committee approval
11/16/2010	Medical Policy Implementation Committee approval. No change to coverage eligibility.
11/03/2011	Medical Policy Committee approval
11/16/2011	Medical Policy Implementation Committee approval. No change to coverage eligibility.
11/01/2012	Medical Policy Committee review
11/28/2012	Medical Policy Implementation Committee approval. Postpartum uterine hemorrhage added to eligible for coverage 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 eligible for coverage with a <i>Note</i> following the coverage statement.
11/07/2013	Medical Policy Committee review
11/20/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/05/2015	Medical Policy Committee review
02/18/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
02/04/2016	Medical Policy Committee review.
02/17/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
02/02/2017	Medical Policy Committee review.
02/15/2017	Medical Policy Implementation Committee approval. Adenomyosis and uterine arteriovenous malformation added to investigational policy statement.
02/01/2018	Medical Policy Committee review.

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Louisiana

Occlusion of Uterine Arteries Using Transcatheter Embolization

Policy # 00130

Original Effective Date: 03/25/2002

Current Effective Date: 03/09/2020

- 02/21/2018 Medical Policy Implementation Committee approval. Removed “Based on review of available data, the Company considers laparoscopic occlusion of the uterine arteries using bipolar coagulation to be investigational” from coverage statement.
- 02/07/2019 Medical Policy Committee review.
- 02/20/2019 Medical Policy Implementation Committee approval. No change to coverage.
- 02/06/2020 Medical Policy Committee review.
- 02/12/2020 Medical Policy Implementation Committee approval. Title changed from “Occlusion of Uterine Arteries Using Transcatheter Embolization or Laparoscopic Occlusion to Treat Uterine Fibroids” to “Occlusion of Uterine Arteries Using Transcatheter Embolization”.

Next Scheduled Review Date: 02/2021

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	37243, 37244
HCPCS	No codes
ICD-10 Diagnosis	D25.0-D25.9, N80.0-N80.9, O00.80-O00.81, O43.211-O43.213, O43.221-O43.223, O43.231-O43.233, O72.0-O72.2, Q27.30, Q27.39

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;

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- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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