Transcatheter Uterine Artery Embolization

Policy # 00130
Original Effective Date: 03/25/2002
Current Effective Date: 05/01/2024

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 Are 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.*

Based on review of available data, the Company may consider transcatheter uterine artery embolization in certain situations as a technique to control acute pelvic hemorrhagic conditions from something other than uterine fibroids, such as obstetric hemorrhage or ectopic pregnancy to be **eligible for coverage.****

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.*

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

Patient Selection Criteria

Coverage eligibility for transcatheter uterine artery embolization as a treatment of uterine fibroids will be considered when any of the following criteria are met:

- Excessive uterine bleeding; **or**

- Pelvic discomfort caused by uterine fibroids (for example, acute severe pain, chronic lower abdominal pain, low back pressure, or bladder pressure with urinary frequency not due to urinary tract infection).

When Services Are Considered Investigational

Based on review of available data, the Company considers transcatheter uterine artery embolization in all other situations and when criteria above have not been met to be **investigational.***

Based on review of available data, the Company considers repeat transcatheter embolization of uterine arteries to treat persistent symptoms of uterine fibroids after an initial uterine artery embolization to be **investigational.***

Background/Overview

This document addresses the use of transcatheter uterine artery embolization (UAE) as a treatment for fibroid tumors. UAE is a pelvic angiographic procedure used to decrease the symptoms of heavy bleeding and pelvic pain associated with fibroid tumors. Using hemostatic particles, selected vasculature providing the blood supply to the fibroids are occluded. When the blood supply is occluded, the fibroids decrease in size, thereby reducing the symptoms.

Transcatheter UAE has also been used for treatment of other acute pelvic hemorrhagic conditions such as uterine hemorrhage and ectopic pregnancy. Transcatheter uterine artery embolization is a technique performed by an interventional radiologist.

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 otherdevices 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 peripheralhypervascular tumors and peripheral AVMs. In March 2004, the Contour SE™‡ (Boston Scientific) was cleared formarketing by the FDA through the 510(k) process for the treatment of uterine fibroids. In 2008, Polyvinyl Alcohol FoamEmbolization Particles (Cook Inc.) was cleared for marketing by the FDA through the 510(k) process for use in uterinefibroid embolization. In 2016, Bead Block™‡ microspheres (Biocompatibles UK) were cleared for marketing by FDA forembolization of uterine fibroids and AVMs. In 2020, Hydropearl®‡ Microspheres (MicroVention, Inc.) was cleared formarketing by FDA for the embolization of arteriovenous malformations and hypervascular tumors, including uterinefibroids. FDA product code: NAJ.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Transcatheter UAE deprives blood flow to uterine fibroids by embolizing the blood supply to the fibroids using a catheter placed into an artery (usually the femoral or radial artery) which is directed to the vessels that supply the fibroids. Once localized, the blood supply is blocked (a process called embolization) by injecting one of several substances which cause arterial occlusion, resulting in atrophy and death of the target tissue (fibroid) over a period of weeks or months. UAE has been reported to have a success rate of 81-100% (American College of Radiology [ACR], 2017).

UAE for Uterine Fibroids

Randomized controlled trials and meta-analyses provided early outcomes comparing the outcomes of UAE to surgical intervention and characterizing the complications following UAE (Bruijn, 2016; Martin, 2013; Moss, 2011; Torr, 2012). Overall, no significant differences in quality of life (QOL) were observed between UAE and surgery, though reintervention was significantly more likely following UAE. The most frequent adverse effects of UAE included pain, fever, amenorrhea, passage of fibrous tissue and post-embolization syndrome.

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In 2017, the Agency for Healthcare Research and Quality (AHRQ) published a comparative effectiveness review entitled "Management of uterine fibroids." The purpose of the review was to evaluate treatment effectiveness and the risk of leiomyosarcoma in women with fibroids. In regards to UAE, AHRQ concluded:

> There was high strength of evidence that UAE is effective for reducing fibroid volume. The strength of evidence supporting improvements in bleeding and quality of life is moderate for UAE. Five-year follow-up data were available from two large good quality trials in which well over half the women who received an embolization did not need a subsequent intervention (including hysterectomy). The effect of UAE on reproductive outcomes is not well studied and evidence is insufficient to guide care or determine safety.

Laughlin-Tommaso and colleagues (2019) reported on The Fibroid Interventions: Reducing Symptoms Today and Tomorrow (FIRSTT) randomized controlled trial. The trial's primary aim was to compare treatment effectiveness between UAE versus magnetic resonance imaging (MRI)-guided ultrasound surgery, and the secondary aim was to compare QOL, pain, fibroid symptom scores, and ovarian function between the two treatments for uterine leiomyomas. A total of 83 individuals were treated with 43 individuals in the MRI-guided ultrasound surgery group and 40 individuals in the UAE group. Of those in the MRI-guided ultrasound group, 16 (37%) individuals accepted enrollment in the study, but declined randomization, and of those in the UAE group, 18 (45%) individuals accepted enrollment in the study, but declined randomization. The results showed the rate of secondary procedure was higher in the MRI-guided ultrasound surgery group (30%) than the UAE group (13%) (hazard ratio, 2.81; 95% Confidence Interval [CI], 1.01-7.79). Secondary procedures included hysterectomy, myomectomy, and UAE. Ovarian function was evaluated by measuring serum anti-Müllerian hormone (AMH). At 24 months, the median interquartile range absolute change in AMH was significantly larger in the UAE group (-0.6 units [-1.2-0.4]) than the MRI-guided ultrasound surgery group (-0.2 units [-0.4-0.4]; p=0.03). Overall, QOL, pain, and fibroid symptom scores improved in both groups with a higher improvement in the UAE group; however, there was incomplete follow-up in both groups with only 44% follow-up in the MRI-guided ultrasound surgery group and 55% follow-up in the UAE group. This study shows positive results for UAE; however, a few limitations to note are the small sample size, partial randomization, and incomplete follow-up assessments of QOL, pain, and fibroid symptom scores.

In 2020, Manyonda and colleagues published the results of a multicenter, randomized, open-label trial which enrolled 254 premenopausal women, 18 or older, to evaluate myomectomy (n=105)

compared to UAE (n=98), in those with symptomatic uterine fibroids who wanted to avoid hysterectomy. The study's primary outcome of interest was fibroid-related QOL. Secondary measures included menstrual blood loss estimation by self-report, occurrence of pregnancy and pregnancy outcomes, and overall satisfaction with the procedure. A total of 206 women (81%) were available for evaluation of the primary outcome. At 2 years, the mean score on the health-related QOL domain of the UFS-QOL questionnaire was 84.6 (standard deviation [SD] 21.5) in the myomectomy group and 80.0 (SD 22.0) in the UAE group (p=0.01). Perioperative and postoperative complications occurred in 29% of the women in the myomectomy group and in 24% of the women in the UAE group (relative risk, 1.2; 95% CI, 0.8 to 1.9; p=0.40). At 2-year follow-up, additional fibroid-related procedures were performed in 16% of the UAE group and 7% of the myomectomy group. The median length of hospital stay was 2 days for the UAE group and 4 days for the myomectomy group. There were too few pregnancies during the trial to compare differences, if any, in fertility-sparing outcomes following the procedures. With respect to the study's primary outcome, authors conclude that, among women with symptomatic uterine fibroids, treatment with myomectomy resulted in better fibroid-related QOL at 2 years compared to treatment with UAE. Both UAE and myomectomy remain reasonable options for women seeking uterine-sparing treatment of symptomatic uterine fibroids.

Based on evaluation of the existing peer-reviewed medical literature, there is adequate evidence to support the use of UAE for the treatment of acute pelvic and obstetric hemorrhage, ectopic pregnancy, and symptomatic uterine fibroids (including pedunculated fibroids [Katsumori, 2005; Kim, 2018; Smeets, 2009; Zhang, 2022]). For the treatment of pelvic and obstetric hemorrhage, UAE has been shown to be a safe and effective method to control bleeding when compared with alternative methods, such as surgical intervention. For ectopic pregnancy, it has been illustrated that UAE is a safe and effective adjunct to methotrexate treatment, decreasing the need for surgical interventions following drug-only treatment methods that are often unsuccessful.

Repeat UAE for Uterine Fibroids

Due to a paucity of data, the current literature evaluating clinical outcomes following repeat UAE for treatment of persistent symptoms of uterine fibroids after an initial UAE is insufficient to establish efficacy (McLucas, 2009; Yousefi, 2006).

Contraindications to UAE

Andrews and colleagues (2004) cite contraindications for uterine artery embolization to include pregnancy, infection, malignancy, coagulopathy and prior pelvic irradiation. The Society of Obstetricians and Gynaecologists of Canada stated in a guideline entitled "The management of uterine leiomyomas" the following recommendations regarding UAE:

> Uterine artery occlusion by embolization or surgical methods may be offered to selected women with symptomatic uterine fibroids who wish to preserve their uterus. Women choosing uterine artery occlusion for the treatment of fibroids should be counselled regarding possible risks, including the likelihood that fecundity and pregnancy may be impacted.

An increase in uterine size due to fibroid volume is a consideration prior to UAE. A study by Choi (2013) evaluated the safety, effectiveness, and rate of complications of UAE in women with large uterine fibroids. A total of 323 women without adenomyosis underwent UAE for symptomatic uterine fibroids. The women were divided into 2 groups: group 1 (treatment group) included 63 women with a large tumor of at least 10 cm in size or a uterine volume of at least 700 cm and group 2 (260 women) was the control group. Group 1 demonstrated a 46.5% tumor volume reduction compared with 52% in group 2. Group 1 had a 40.7% uterine volume reduction compared with 36.3% in group 2. There were no reported significant differences in satisfaction or the presence of procedure-related complications.

Other therapies for symptomatic uterine fibroids include hysterectomy, myomectomy, hormonal therapy with gonadotropin-releasing hormone (GnRH) analogues and luteinizing-hormone releasing hormone (LHRH) analogues, and endurance until menopause when fibroids often regress.

UAE for Adenomyosis

The current published literature does not support the use of UAE for adenomyosis. A review by Popovic (2011) evaluated 15 studies in which 511 women received UAE for adenomyosis. Although 387 of the 511 women reported symptomatic relief, the authors of the review concluded that the evidence is insufficient to establish UAE as a potential first-line treatment for adenomyosis. Larger, randomized trials with sufficient follow-up periods are necessary to determine true value of UAE. In 2012, the ACR revised its Appropriateness Criteria®‡ for the Radiologic Management of Uterine Leiomyomas and concluded that "UAE has shown early success in controlling the symptoms of bleeding with adenomyosis." However, there is a recurrence rate of approximately 40%-50% at 2 years and the long-term durability of UAE is questionable. This was reaffirmed in 2017.

A retrospective study by Smeets (2012) reported on 40 women with adenomyosis who were treated with UAE. Mean clinical follow-up was 65 months. A total of 8 women required additional therapy due to insufficient symptom relief (7 hysterectomies and 1 repeat UAE). Follow-up consisted of the use of uterine fibroid symptom relief and QOL questionnaires. Of the 33 women with a preserved uterus who responded to QOL questionnaires, 29 had scores indicating they were asymptomatic, and 4 women had scores indicating substantial clinical symptoms despite embolization. This study is limited by its small sample size and retrospective design.

In 2017, de Bruijn and colleagues published a systematic review and meta-analysis with the aim to evaluate UAE for the treatment of adenomyosis. The study selection process yielded 30 studies, which were mainly comprised of retrospective studies with small sample sizes and unclear methodologies. While the authors found an improvement of symptoms in 872 individuals (83.1%) and a reduction of uterine volume in all individuals at 3 months, there were complications in 615 individuals (59%). The authors concluded that UAE could be a treatment alternative to hysterectomy; however, randomized controlled trials are needed to confirm this conclusion. Other study limitations include possible selection bias and lack of comparison to other treatments in the included studies.

Supplemental Information/Definitions

Adenomyosis: A benign uterine disease in which the endometrium invades the myometrium resulting in enlargement of the uterus, menorrhagia and dysmenorrhea.

Ectopic pregnancy: A pregnancy which occurs when a fertilized egg becomes implanted outside the uterus in locations such as the fallopian tubes, cervix, ovaries or in the pelvic or abdominal space.
Embolization: The insertion of a substance through a catheter into a blood vessel to prevent the flow of blood.

Myomectomy: Procedure in which uterine fibroids are surgically removed from the uterus.
Pedunculated fibroid: Benign (noncancerous) growths in the uterus (fibroids) attached to the uterine wall by a stalk-like growth called a peduncle.

Post-embolization syndrome: A frequent occurrence following uterine artery embolization which peaks about 48 hours post-procedure and is characterized by low-grade fever, pain, fatigue, nausea and vomiting.

Uterine fibroids: Common and benign (non-cancerous) tumors of the uterus (also known as leiomyomata).

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Government Agency, Medical Society, and Other Authoritative Publications:

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Policy History

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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

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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.
11/05/2008	Medical Director review
11/18/2008	Medical Policy Committee approval. No change to coverage eligibility.
11/12/2009	Medical Policy Committee approval
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 *Note* 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

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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.
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".
02/04/2021	Medical Policy Committee review.
02/10/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/03/2022	Medical Policy Committee review.
02/09/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/02/2023	Medical Policy Committee review.
02/08/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/01/2024	Medical Policy Committee review.

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02/14/2024 Medical Policy Implementation Committee approval. Policy extensively rewritten. Title changed from Occlusion of Uterine Arteries Using Transcatheter Embolization to Transcatheter Uterine Artery Embolization.
Next Scheduled Review Date: 02/2025

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 2023 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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CPT is a registered trademark of the American Medical Association.

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

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ICD-10 Diagnosis	All related Diagnoses

*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 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;
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: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.