

FEP 4.01.11 Occlusion of Uterine Arteries Using Transcatheter Embolization

Effective Date: January 15, 2019

Related Policies:

4.01.19 Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids
7.01.109 MRI-Guided Focused Ultrasound (MRgFUS) for the Treatment of Uterine Fibroids and Other Tumors

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**.

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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 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 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 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

Summary of Evidence

For individuals who have uterine fibroids who receive transcatheter UAE, the evidence includes randomized controlled trials 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 uterus, 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

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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. 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. 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. 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.

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SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Obstetricians and Gynecologists

The American College of Obstetricians and Gynecologists (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 uterine artery embolization (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.”

ACOG (2013) issued a committee opinion on the management of acute abnormal uterine bleeding in nonpregnant reproductive-aged women.³⁸ This opinion was reaffirmed in 2017. 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.

ACOG (2017) published a practice bulletin (No. 183) on 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 Obstetricians and Gynecologists of Canada

The Society of Obstetricians and Gynecologists of Canada (2015) published clinical guidelines on the management of uterine leiomyomas.⁴⁰ The guidelines stated: “Of the conservative interventional treatments currently available, uterine artery embolization has the longest track record and has been shown to be effective in properly selected patients.”

Society of Interventional Radiology

The 2010 (reviewed and unchanged in 2014) quality improvement guidelines from the Society of Interventional Radiology stated that UAE is indicated in women with uterine leiomyomas causing significant symptoms.⁴¹ 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.⁴² 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.

Medicare National Coverage

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

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REFERENCES

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Uterine artery embolization for treatment of symptomatic uterine fibroids. *TEC Assessments*. 2002;Volume 17:Tab 8.
2. Gupta JK, Sinha A, Lumsden MA, et al. Uterine artery embolization for symptomatic uterine fibroids. *Cochrane Database Syst Rev*. Dec 26 2014;12(12):CD005073. PMID 25541260
3. Das R, Champaneria R, Daniels JP, et al. Comparison of embolic agents used in uterine artery embolisation: a systematic review and meta-analysis. *Cardiovasc Intervent Radiol*. Oct 2014;37(5):1179-1190. PMID 24305981
4. Martin J, Bhanot K, Athreya S. Complications and reinterventions in uterine artery embolization for symptomatic uterine fibroids: a literature review and meta analysis. *Cardiovasc Intervent Radiol*. Apr 2013;36(2):395-402. PMID 23152035
5. van der Kooij SM, Bipat S, Hehenkamp WJ, et al. Uterine artery embolization versus surgery in the treatment of symptomatic fibroids: a systematic review and metaanalysis. *Am J Obstet Gynecol*. Oct 2011;205(4):317 e311-318. PMID 21641570
6. Edwards RD, Moss JG, Lumsden MA, et al. Uterine-artery embolization versus surgery for symptomatic uterine fibroids. *N Engl J Med*. Jan 25 2007;356(4):360-370. PMID 17251532
7. Moss JG, Cooper KG, Khaund A, et al. Randomised comparison of uterine artery embolisation (UAE) with surgical treatment in patients with symptomatic uterine fibroids (REST trial): 5-year results. *Bjog*. Jul 2011;118(8):936-944. PMID 21481151
8. Hehenkamp WJ, Volkers NA, Donderwinkel PF, et al. Uterine artery embolization versus hysterectomy in the treatment of symptomatic uterine fibroids (EMMY trial): peri- and postprocedural results from a randomized controlled trial. *Am J Obstet Gynecol*. Nov 2005;193(5):1618-1629. PMID 16260201
9. Volkers NA, Hehenkamp WJ, Birnie E, et al. Uterine artery embolization versus hysterectomy in the treatment of symptomatic uterine fibroids: 2 years' outcome from the randomized EMMY trial. *Am J Obstet Gynecol*. Jun 2007;196(6):519 e511-511. PMID 17547877
10. van der Kooij SM, Hehenkamp WJ, Volkers NA, et al. Uterine artery embolization vs hysterectomy in the treatment of symptomatic uterine fibroids: 5-year outcome from the randomized EMMY trial. *Am J Obstet Gynecol*. Aug 2010;203(2):105 e101-113. PMID 20579960
11. de Bruijn AM, Ankum WM, Reekers JA, et al. Uterine artery embolization vs hysterectomy in the treatment of symptomatic uterine fibroids: 10-year outcomes from the randomized EMMY trial. *Am J Obstet Gynecol*. Dec 2016;215(6):745 e741-745 e712. PMID 27393268
12. Manyonda IT, Bratby M, Horst JS, et al. Uterine artery embolization versus myomectomy: impact on quality of life--results of the FUME (Fibroids of the Uterus: Myomectomy versus Embolization) Trial. *Cardiovasc Intervent Radiol*. Jun 2012;35(3):530-536. PMID 21773858
13. Hald K, Klow NE, Qvigstad E, et al. Laparoscopic occlusion compared with embolization of uterine vessels: a randomized controlled trial. *Obstet Gynecol*. Jan 2007;109(1):20-27. PMID 17197583
14. Hald K, Noreng HJ, Istre O, et al. Uterine artery embolization versus laparoscopic occlusion of uterine arteries for leiomyomas: long-term results of a randomized comparative trial. *J Vasc Interv Radiol*. Oct 2009;20(10):1303-1310; quiz 1311. PMID 19713130
15. Barnard EP, AbdElmagied AM, Vaughan LE, et al. Periprocedural outcomes comparing fibroid embolization and focused ultrasound: a randomized controlled trial and comprehensive cohort analysis. *Am J Obstet Gynecol*. May 2017;216(5):500 e501-500 e511. PMID 28063909
16. McLucas B, Reed RA. Repeat uterine artery embolization following poor results. *Minim Invasive Ther Allied Technol*. Jan 2009;18(2):82-86. PMID 19177259
17. Yousefi S, Czeyda-Pommersheim F, White AM, et al. Repeat uterine artery embolization: indications and technical findings. *J Vasc Interv Radiol*. Dec 2006;17(12):1923-1929. PMID 17185687
18. Mara M, Maskova J, Fucikova Z, et al. Midterm clinical and first reproductive results of a randomized controlled trial comparing uterine fibroid embolization and myomectomy. *Cardiovasc Intervent Radiol*. Jan-Feb 2008;31(1):73-85. PMID 17943348
19. Sathe NA, Likis FE, Young JL, et al. Procedures and uterine-sparing surgeries for managing postpartum hemorrhage: a systematic review. *Obstet Gynecol Surv*. Feb 2016;71(2):99-113. PMID 26894802
20. Rath W, Hackethal A, Bohlmann MK. Second-line treatment of postpartum haemorrhage (PPH). *Arch Gynecol Obstet*. Sep 2012;286(3):549-561. PMID 22552376
21. Kim TH, Lee HH, Kim JM, et al. Uterine artery embolization for primary postpartum hemorrhage. *Iran J Reprod Med*. Jun 2013;11(6):511-518. PMID 24639786

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22. Ganguli S, Stecker MS, Pyne D, et al. Uterine artery embolization in the treatment of postpartum uterine hemorrhage. *J Vasc Interv Radiol*. Feb 2011;22(2):169-176. PMID 21183360
23. Kirby JM, Kachura JR, Rajan DK, et al. Arterial embolization for primary postpartum hemorrhage. *J Vasc Interv Radiol*. Aug 2009;20(8):1036-1045. PMID 19647182
24. Doumouchtsis SK, Nikolopoulos K, Talaulikar V, et al. Menstrual and fertility outcomes following the surgical management of postpartum haemorrhage: a systematic review. *Bjog*. Mar 2014;121(4):382-388. PMID 24321038
25. Mohan PP, Hamblin MH, Vogelzang RL. Uterine artery embolization and its effect on fertility. *J Vasc Interv Radiol*. Jul 2013;24(7):925-930. PMID 23701904
26. Kwon JH, Kim GM, Han K, et al. Safety and efficacy of uterine artery embolization in ectopic pregnancies refractory to systemic methotrexate treatment: a single-center study. *Cardiovasc Intervent Radiol*. May 01 2017;40(9):1351-1357. PMID 28462440
27. Hu J, Tao X, Yin L, et al. Successful conservative treatment of cervical pregnancy with uterine artery embolization followed by curettage: a report of 19 cases. *BJOG*. Sep 2016;123 Suppl 3:97-102. PMID 27627607
28. Xiaolin Z, Ling L, Chengxin Y, et al. Transcatheter intraarterial methotrexate infusion combined with selective uterine artery embolization as a treatment option for cervical pregnancy. *J Vasc Interv Radiol*. Jun 2010;21(6):836-841. PMID 20400332
29. Yoon DJ, Jones M, Taani JA, et al. A systematic review of acquired uterine arteriovenous malformations: pathophysiology, diagnosis, and transcatheter treatment. *AJP Rep*. Mar 2016;6(1):e6-e14. PMID 26929872
30. Barral PA, Saeed-Kilani M, Tradi F, et al. Transcatheter arterial embolization with ethylene vinyl alcohol copolymer (Onyx) for the treatment of hemorrhage due to uterine arteriovenous malformations. *Diagn Interv Imaging*. May 2017;98(5):415-421. PMID 27776896
31. Kim T, Shin JH, Kim J, et al. Management of bleeding uterine arteriovenous malformation with bilateral uterine artery embolization. *Yonsei Med J*. Mar 2014;55(2):367-373. PMID 24532505
32. Popovic M, Puchner S, Berzaczy D, et al. Uterine artery embolization for the treatment of adenomyosis: a review. *J Vasc Interv Radiol*. Jul 2011;22(7):901-909; quiz 909. PMID 21570318
33. de Bruijn AM, Smink M, Hehenkamp WJK, et al. Uterine artery embolization for symptomatic adenomyosis: 7-year clinical follow-up using UFS-QoL Questionnaire. *CardioVascular and Interventional Radiology*. May 17 2017;40(9):1344-1350. PMID 28516272
34. Zhou J, He L, Liu P, et al. Outcomes in adenomyosis treated with uterine artery embolization are associated with lesion vascularity: a long-term follow-up study of 252 cases. *PLoS One*. Nov 2 2016;11(11):e0165610. PMID 27806072
35. Wang S, Meng X, Dong Y. The evaluation of uterine artery embolization as a nonsurgical treatment option for adenomyosis. *Int J Gynaecol Obstet*. May 2016;133(2):202-205. PMID 26868068
36. Bae SH, Kim MD, Kim GM, et al. Uterine artery embolization for adenomyosis: percentage of necrosis predicts midterm clinical recurrence. *J Vasc Interv Radiol*. Sep 2015;26(9):1290-1296 e1292. PMID 26074028
37. American College of Obstetricians Gynecologists. ACOG practice bulletin. Alternatives to hysterectomy in the management of leiomyomas. *Obstet Gynecol*. Aug 2008;112(2 Pt 1):387-400. PMID 18669742
38. American College of Obstetricians and Gynecologists (ACOG). Committee Opinion Number 557: Management of Acute Abnormal Uterine Bleeding in Non-Pregant, Reproductive-Aged Women. Number 557. 2013; <http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Management-of-Acute-Abnormal-Uterine-Bleeding-in-Nonpregnant-Reproductive-Aged-Women>. Accessed July 16, 2018.
39. Committee on Practice Bulletins-Obstetrics. Practice Bulletin No. 183: Postpartum hemorrhage. *Obstet Gynecol*. Oct 2017;130(4):e168-e186. PMID 28937571
40. Vilos GA, Allaire C, Laberge PY, et al. The management of uterine leiomyomas. *J Obstet Gynaecol Can*. Feb 2015;37(2):157-181. PMID 25767949
41. Dariushnia SR, Nikolic B, Stokes LS, et al. Quality improvement guidelines for uterine artery embolization for symptomatic leiomyomata. *J Vasc Interv Radiol*. Nov 2014;25(11):1737-1747. PMID 25442136
42. Expert Panel on Interventional R, Knuttinen MG, Stark G, et al. ACR Appropriateness Criteria((R)) radiologic management of uterine leiomyomas. *J Am Coll Radiol*. May 2018;15(5S):S160-S170. PMID 29724419

POLICY HISTORY

Date	Action	Description
December 2011	New Policy	

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

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December 2012	Update 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	Update 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	Update Policy	Policy updated with literature review. Uterine arteriovenous malformation added to investigational policy statement. References 15-17 and 21-22 added
September 2015	Update Policy	Policy updated with literature review; references 2 and 31-32 added. Policy statements unchanged.
September 2016	Update Policy	Policy updated with literature review; references 11, 17, 26, and 28-30 added. Adenomyosis added to investigational policy statement.
December 2018	Update Policy	Policy updated with literature review through June 4, 2018; references 15, 26-27, 30, 33-34, 39 and 42 added. Policy statements unchanged

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