02-56000-26

Original Effective Date: 04/17/00

Reviewed: 09/26/24

Revised: 10/15/24

Subject: Occlusion of Uterine Arteries Using Transcatheter Embolization

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
<u>Other</u>	References	<u>Updates</u>			

DESCRIPTION:

Transcatheter uterine artery embolization (UAE) is a minimally invasive technique that involves the injection of small particles into the uterine arteries to block the blood supply to the uterus and uterine fibroids.

Transcatheter uterine artery embolization (UAE), also known as uterine fibroid embolization (UFE) is a minimally invasive endovascular procedure. UAE involves the use of angiographic guidance for selective catherization of the uterine arteries with injection of an embolization material to block the arteries that provide blood flow, causing the fibroid to shrink. Transcatheter uterine artery embolization has been used to treat postpartum hemorrhage.

Laparoscopic uterine artery occlusion has been investigated as an alternative to UAE. With laparoscopic uterine artery occlusion, multiple laparoscopic laser punctures of the uterine fibroid are performed in an effort to devascularize the fibroid and induce <u>atrophy</u>.

Several embolization devices are approved by the Food and Drug Administration (FDA) (e.g., Embosphere® Microspheres (Merit Medical, formerly BioSphere Medical), Contour® PVA (Boston Scientific), Contour SE[™] (Boston Scientific), Polyvinyl Alcohol Foam Embolization Particles (Cook Inc.)).

Summary and Analysis of Evidence: An UpToDate review on "Treatment with uterine embolication" (van der Kooij) states Uterine artery embolization (UAE) was introduced for the treatment of symptomatic uterine fibroids (leiomyomas) in 1995. UAE treatment of fibroids is performed worldwide. Fibroids are a common gynecologic problem and result in symptoms that impact quality of life and may result in anemia or other adverse effects. There are many options for treatment, including hormonal therapy, hysteroscopic or abdominal myomectomy, and hysterectomy. UAE provides a minimally

invasive and uterine-sparing treatment option. UAE is a treatment option for patients with symptomatic uterine leiomyomas. Ideal candidates for UAE include patients with all of the following characteristics: heavy menstrual bleeding or dysmenorrhea caused by intramural fibroids, premenopausal and no desire for future pregnancy. For patients with these characteristics, a high symptom control rate, satisfaction, and quality of life can be achieved for up to 10 years after treatment. If bulk-related symptoms (e.g., sensation of pressure in the lower abdomen, nocturia, urinary frequency, and urinary incontinence) are the only symptoms, the efficacy of UAE is questionable. The embolization versus hysterectomy randomized trial (EMMY) showed no significant improvement compared with baseline in bulk-related complaints. Some prospective cohort studies have found, however, a significant improvement in bulkrelated symptoms even in the long-term. It is also not usually used to treat infertility related to fibroids, since a desire for future childbearing is a relative contraindication. UAE is also a potential option for treatment of uterine adenomyosis, but the data are limited regarding efficacy for this indication. A literature review included 1049 patients with adenomyosis treated with UAE and reported significant improvement in symptoms in 83.1 percent of patients. Uteri with adenomyosis combined with fibroids tend to have better results than uteri with only adenomyosis. However, these were low-guality data from series with no control group. The American College of Obstetricians and Gynecologists states that the effect of UAE on pregnancy remains understudied but makes no recommendation of whether desire for a future pregnancy is a contraindication. The procedure is indicated primarily for premenopausal patients since fibroids tend to decrease in size and symptoms improve or resolve after menopause. An enlarging uterus after menopause should raise the suspicion of a malignancy and careful follow-up is warranted. UAE is also a potential option for treatment of uterine adenomyosis, but the data are limited regarding efficacy for this indication. A literature review included 1049 patients with adenomyosis treated with UAE and reported significant improvement in symptoms in 83.1 percent of patients. Uteri with adenomyosis combined with fibroids tend to have better results than uteri with only adenomyosis. However, these were low-quality data from series with no control group. Management of uterine adenomyosis is discussed in detail separately. There are limited data regarding prognostic factors to predict the effect of UAE on fibroid volume, symptoms, and need for reintervention. The largest studies did not show strong predictors, and some smaller studies have reported predictors, but these may be underpowered.

Liu et al. (2024) conducted a prospective study to compare ovarian function of women with uterine fibroids who did or did not undergo uterine artery embolization (UAE). This prospective cohort study enrolled 87 women with symptomatic uterine fibroids who underwent UAE, and 87 women with the same symptoms who did not undergo UAE but received conservative management or other treatments. The two groups were matched for age, body mass index, parity, and baseline characteristics of uterine fibroids. The primary outcome was ovarian function that was evaluated by serum levels of follicle-stimulating hormone (FSH), luteinizing hormone (LH), estradiol (E2), and anti-Müllerian hormone (AMH), as well as ovarian reserve tests, such as antral follicle count (AFC) and ovarian volume (OV). The secondary outcome was fertility that was evaluated based on the menstrual cycle, ovulation, conception, pregnancy, and delivery. The participants were followed-up for 36 months and assessed at 1, 3, 6, 12, 24, and 36 months after treatment. The study found that the most common minor complication of UAE was postembolization syndrome in 73.6% of women, resolving within a week. No significant differences were observed between the UAE group and the control group in serum levels of reproductive hormones (FSH, LH, E2, AMH) and ovarian reserve indicators (AFC, OV) at any point up to 36 months post-treatment. Additionally, there were no significant differences in conception, pregnancy,

or delivery rates, with the average time to conception and gestational age at delivery being similar between the two groups. Birth weights were also comparable. Finally, there was no significant correlation between ovarian function, fertility indicators, and the type or amount of embolic agent used or the change in fibroids post-treatment. The authors concluded UAE resulted in significantly positive pregnancy outcomes, no adverse events post-treatment, and is a safe and effective treatment for uterine fibroids that preserves ovarian function and fertility.

de Bruijn et al. (2016) conducted a rabdomized controlled trial to compare clinical outcome and healthrelated quality of life 10 years after uterine artery embolization or hysterectomy in the treatment of heavy menstrual bleeding caused by uterine fibroids in a randomized controlled trial. Tewnty-eight Dutch hospitals recruited patients with symptomatic uterine fibroids who were eligible for hysterectomy. Patients were 1:1 randomly assigned to uterine artery embolization or hysterectomy. The outcomes assessed at 10 years postintervention were reintervention rates, health-related quality of life, and patient satisfaction, which were obtained through validated questionnaires. Study outcomes were analyzed according to original treatment assignment (intention to treat). A total of 177 patients were randomized from 2002 through 2004. Eventually 81 uterine artery embolization and 75 hysterectomy patients underwent the allocated treatment shortly after randomization. The remaining patients withdrew from the trial. The 10-year questionnaire was mailed when the last included patient had been treated 10 years earlier. The mean duration of follow-up was 133 months (SD 8.58) accompanied by a mean age of 57 years (SD 4.53). Questionnaires were received from 131 of 156 patients (84%). Ten years after treatment, 5 patients underwent secondary hysterectomy resulting in a total of 28 of 81 (35%) (24/77 [31%] after successful uterine artery embolization). Secondary hysterectomies were performed for persisting symptoms in all cases but 1 (for prolapse). After the initial treatment health-related quality of life improved significantly. After 10 years, generic health-related quality of life remained stable, without differences between both groups. The urogenital distress inventory and the defecation distress inventory showed a decrease in both groups, probably related to increasing age, without significant differences between study arms. Satisfaction in both groups remained comparable. The majority of patients declared being (very) satisfied about the received treatment: 78% of the uterine artery embolization group vs 87% in the hysterectomy group. The authors concluded in about two thirds of uterine artery embolization-treated patients with symptomatic uterine fibroids a hysterectomy can be avoided. Health-related quality of life 10 years after uterine artery embolization or hysterectomy remained comparably stable. Uterine artery embolization is a well-documented and less invasive alternative to hysterectomy for symptomatic uterine fibroids on which eligible patients should be counseled.

The literature on cryomyolysis, laparoscopic bipolar coagulation and MR guided laser ablation is limited. A larger series and longer follow-up are required to evaluate long-term effects and to identify appropriate individuals. (Hindley et al. 2002, Liu et al. 2000, Zupi et al. 2004; 2005).

POSITION STATEMENT:

Transcatheter embolization of uterine arteries **meets the definition of medical necessity** for the treatment of:

- Uterine fibroids;
- Postpartum uterine hemorrhage.

One repeat transcatheter embolization of uterine arteries to treat persistent symptoms (e.g., bleeding, pain) of uterine fibroids after an initial uterine artery embolization **meets the definition of medical necessity**.

Transcatheter embolization of uterine arteries for the management of all other indications is considered **experimental or investigational**. The evidence is insufficient to determine the effects of the technology on health outcomes.

Laparoscopic and percutaneous occlusion and techniques (e.g., radiofrequency ablation, laser ablation, bipolar needles, cryomyolysis) of the uterine arteries for all indications is considered **experimental or investigational**. The evidence is insufficient to support conclusions regarding effects on health outcomes.

BILLING/CODING INFORMATION:

There is no specific CPT or HCPCS code to report transcatheter embolization of uterine arteries.

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

DEFINITIONS:

Atrophy: a wasting away; a diminution in the size of a cell, tissue, organ, or part.

Dysmenorrhea: painful menstruation.

Leiomyomata: leiomyomata of the uterus usually occurring in the third and fourth decades of life, characterized by multiple, firm, round, sharply circumscribed, unencapsulated, gray to white tumors that show a whorled pattern on cut section. The majority are within the myometrium of the corpus of the uterus, but they may also occur in the cervix, usually in its posterior wall.

Menorrhagia: menstruation with an excessive flow but at regular intervals and of usual duration.

Myomectomy: surgical excision of a uterine myoma (leiomyoma).

RELATED GUIDELINES:

None applicable.

OTHER:

Other names used to report transcatheter uterine artery embolization:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Uterine fibroid embolization (UFE) Transcatheter embolization

REFERENCES:

- 1. Agency for Healthcare Research and Quality (AHRQ). U.S. Department of Health and Human Services Evidence Report/Technology Assessment Number 154. Management of Uterine Fibroids: An Update of the Evidence, 07/07.
- 2. American College of Obstetricians and Gynecologists (ACOG) Committee Opinion No. 293. Uterine Artery Embolization, 2004.
- 3. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin. Alternatives to hysterectomy in the management of leiomyomas. Obstetrics and Gynecology 2008; 96: 387-399.
- 4. Andrews RT, Spies JB, Sacks D et al. Standards of Practice patient care and uterine artery embolization for leiomyomata, Journal of Vascular and Interventional Radiology, 2004.
- 5. Beinfeld MT, Bosch JL, Isaacson KB et al. Cost-effectiveness of uterine artery embolization and hysterectomy for uterine fibroids. Radiology 2004; 230(1): 207-213.
- Blue Cross Blue Shield Association Evidence Positioning System[®]. 4.01.11 Occlusion of Uterine Arteries Using Transcatheter Embolization or Laparoscopic Occlusion to Treat Uterine Fibroids, 10/20.
- 7. Blue Cross Blue Shield Association Evidence Positioning System®. 4.01.19 Laparoscopic and Percutaneous, and Transcervical Techniques for Uterine Fibroid Myolysis, 03/24.
- Bradley LD, Pasic RP, Miller LE. Clinical Performance of Radiofrequency Ablation for Treatment of Uterine Fibroids: Systematic Review and Meta-Analysis of Prospective Studies. J Laparoendosc Adv Surg Tech A. 2019 Dec;29(12):1507-1517.
- 9. Committee on Gynecologic Practice, American College of Obstetricians and Gynecologists. ACOG Committee Opinion. Uterine artery embolization. Obstet Gynecol. 2004 Feb;103(2):403-4. [Abstract]
- 10. Dariushnia SR, Nikolic B, Stokes LS et al. Quality improvement guidelines for uterine artery embolization for symptomatic leiomyomata. Journal of Vascular and Interventional Radiology 2014;25(11):1737-1747.
- 11. de Bruijn, 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. American Journal of Obstetrics and Gynecology 2016;215(6):745.e1-745.e12.
- Edwards RG, Moss JG, Lumsden MA et al (The Rest Investigators). Uterine-Artery Embolization versus Surgery for Symptomatic Uterine Fibroids. The New England Journal of Medicine 2007; 356(4): 360-370.
- 13. Evans P, Brunsell S. Uterine Fibroid Tumors: Diagnosis and Treatment. American Family Physicians 2007; 75(10): 1503-1508.
- 14. Gupta JK, Sinha A, Lumsden MA et al. Uterine artery embolization for symptomatic uterine fibroids. Cochrane Database of Systematic Reviews 2014; 26(12): CD005073.

- Goodwin SC, Spies JB, Worthington-Kirsch R et al. Uterine artery embolization for treatment of leiomyomata: long-term outcomes form the FIBROID Registry. Obstetric & Gynecology 2008; 111(1): 22-33.
- 16. Hald K, Klow NE, Qvigstad E et al. Laproscopic occlusion compared with embolization of uterine vessels: a randomized controlled trial. Obstetrics and Gynecology 2007; 109(1): 20-27.
- 17. Havryliuk Y, Setton R, Carlow JJ et al. Symptomatic Fibroid Management: Systematic Review of the Literature. JSLS. 2017;21(3). pii: e2017.00041.
- Hehenkamp WJK, Volkers NA, Birnie E et al. Symptomatic uterine fibroids: Treatment with uterine artery embolization or hysterectomy-Results from the randomized clinical embolisation versus hysterectomy (EMMY) trial. Radiology 2008; 246(3): 823-831.
- 19. Hindley JT, Law PA, Hickey M, et al. Clinical outcomes following percutaneous magnetic resonance image guided laser ablation of symptomatic uterine fibroids. Hum Reprod. 2002 Oct;17(10):2737-41.
- Hirst A, Dutton S, wu O, et al. A multi-centre retrospective cohort study comparing the efficacy, safety and cost-effectiveness of hysterectomy and uterine artery embolisation for the treatment of symptomatic uterine fibroids. The HOPEFUL study. Health Technology Assessment 2008; 12(5): 1-264.
- 21. Keltz J, Levie M, Chudnoff S. Pregnancy Outcomes After Direct Uterine Myoma Thermal Ablation: Review of the Literature. J Minim Invasive Gynecol. 2017 May-Jun;24(4):538-545. [Abstract]
- 22. Kim TH, Lee HH, Kim JM et al. Uterine artery embolization for primary postpartum hemorrhage. Iran Journal of Reproductive Medicine 2013;11(6):511-518.
- 23. Levy, E. B., & Spies, J.B. Transcatheter uterine artery embolization for the treatment of symptomatic uterine fibroid tumors. Journal of Women's Imaging 2000; 2(4): 168-175.
- Lichtinger M, Hallson L, Calvo P et al. Laparoscopic uterine artery occlusion for symptomatic leiomyomas. The Journal of the American Association of Gynecologic Laparoscopists 2002 May; 9(2): 191-198.
- 25. Liu WM. Laparoscopic bipolar coagulation of uterine vessels to treat symptomatic leiomyomas. J Am Assoc Gynecol Laparosc. 2000 Feb;7(1):125-9. [Abstract]
- Liu JL, Liang ZH, Cui B, et al. Impact of uterine artery embolization on ovarian function and pregnancy outcome after uterine-fibroids treatment: A prospective study. World J Clin Cases. 2024 May 26;12(15):2551-2559.
- 27. McLucas B, Reed RA. Repeat uterine artery embolization following poor results. Minimally Invasive Therapy & Allied Technologies 2009;18(2): 82-86.
- 28. National Guideline Clearinghouse-Alternative to hysterectomy in the management of leiomyomas, 01/23/09.
- 29. Stokes LS, Wallace MJ, Godwin RB et al. Quality improvement guidelines for uterine artery embolization for symptomatic leiomyomas. Journal of Vascular and International Radiology 2010; 21(8):1153-1163.
- 30. Taheri M, Galo L, Potts C et al. Nonresective treatments for uterine fibroids: a systematic review of uterine and fibroid volume reductions. Int J Hyperthermia 2019; 36(1): 295-301.
- 31. Tropeano fAmoroso S, Scambia G. Non-surgical management of uterine fibroids. Human Reproduction Update 2008; 14(3): 259-274.
- 32. Van der Kooij SM, Hehenkamp WJ, Vokers NA et al. Uterine artery embolization vs hysterectomy in the treatment of symptomatic uterine fibroids: 5-year outcome from the randomized EMMY trial. American Journal of Obstetrics and Gynecology 2010 Aug; 203(2): 105.e1-105.e13.
- Vilos GA, Allaire C, Laberge PY et al. The management of uterine leiomyomas. Journal of Obstetrics and Gynaecology Canada 2015;37(2):157-81.

- 34. Viswanathan M, Hartmann K, McKoy N et al. Management of uterine fibroids: an update of the evidence. Evidence Report Technology Assessment 2007; (154): 1-122.
- 35. Volkers NA, Hehenkamp JK, Birnie E et al. Uterine artery embolization versus hysterectomy in the treatment of symptomatic uterine fibroids: 2 years' outcome from the randomized EMMY trial. American Journal of Obstetrics & Gynecology 2007; 196(6): 519-521.
- 36. Wong, G. C. H., & Goodwin, S. C. Uterine artery embolization for uterine fibroids. Applied Radiology, 2001; 30(1): 26-31.
- 37. Worthington-Kirsch RL. Uterine Artery Embolization. Endovascular Today 2004; 21-26.
- 38. Zupi E, Marconi D, Sbracia M, et al. Directed laparoscopic cryomyolysis for symptomatic leiomyomata: one-year follow up. J Minim Invasive Gynecol. 2005 Jul-Aug;12(4):343-6. [Abstract]
- 39. Zupi E, Piredda A, Marconi D, et al. Directed laparoscopic cryomyolysis: a possible alternative to myomectomy and/or hysterectomy for symptomatic leiomyomas. Am J Obstet Gynecol. 2004 Mar;190(3):639-43. [Abstract]

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/26/24.

04/17/00	Medical Coverage Guideline Reformatted.
01/01/02	HCPCS coding changes.
08/15/02	Reviewed. Coverage changed from Investigational to Covered based on medical
	necessity.
07/15/04	Scheduled review. Delete reference to InterQual Planning Criteria for myomectomy and
	hysterectomy.
08/15/05	Scheduled review. Added statement considering laparoscopic occlusion with bipolar
	coagulation investigational added. Revised description section. Updated references.
08/15/06	Scheduled review. Revised the definitions for menorrhagia and myomectomy. Updated
	references.
01/01/07	HCPCS update. Added 37210.
04/01/07	HCPCS update. Deleted S2250.
07/15/07	Scheduled review; no change in coverage statements; reformatted guideline.
09/15/08	Scheduled review. No change in position statement. Updated references.
10/15/09	Annual review. Maintain position statements. Updated guideline description section.
	Added "and occlusion of uterine arteries" to guideline subject. Updated references.
01/15/11	Revision; related ICD-10 codes added.
10/15/11	Annual review; maintain position statements. Updated references.
01/01/14	Annual HCPCS coding update; deleted 37210. Revision; Program Exceptions section
	updated.
05/11/14	Revision: Program Exceptions section updated.
04/15/17	Added treatment of postpartum hemorrhage, one repeat transcatheter embolization of
	uterine arteries to treat persistent symptoms (e.g., bleeding, pain) of uterine fibroids

GUIDELINE UPDATE INFORMATION:

	after an initial uterine artery embolization and transcatheter embolization of uterine
	arteries for the management of all other indications.
09/15/19	Review; revised laparoscopic occlusion of the uterine arteries position statement.
	Updated references.
10/15/21	Review; no change to position statement. Updated references.
10/15/23	Review; no change to position statement. Updated references.
10/15/24	Review; no change to position statement. Updated references.