Anthem

Clinical UM Guideline

Subject: Transcatheter Uterine Artery Embolization
Guideline #: CG-SURG-28
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Description

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.

Note: Please see the following related document for additional information:

- MED.00057 MRI Guided High Intensity Focused Ultrasound Ablation for Non-Oncologic Indications

Clinical Indications

Medically Necessary:

A. Transcatheter uterine artery embolization is considered **medically necessary** as a treatment of uterine fibroids when **any** of the following criteria are met:
   1. Excessive uterine bleeding; **or**
   2. 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).

B. Transcatheter uterine artery embolization is considered **medically necessary** 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.

Not Medically Necessary:

A. Transcatheter uterine artery embolization is considered **not medically necessary** when a criterion above has not been met.
B. Repeat transcatheter embolization of uterine arteries to treat persistent symptoms of uterine fibroids after an initial uterine artery embolization is considered **not medically necessary.**

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction [when specified as embolization of uterine artery]
37244	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation [when specified as embolization of uterine artery]
ICD-10 Procedure	
04LE3DT	Occlusion of right uterine artery with intraluminal device, percutaneous approach
04LE3ZT	Occlusion of right uterine artery, percutaneous approach
04LF3DU	Occlusion of left uterine artery with intraluminal device, percutaneous approach
04LF3ZU	Occlusion of left uterine artery, percutaneous approach
ICD-10 Diagnosis	
D25.0-D25.9	Leiomyoma of uterus (fibroids)
N92.0-N92.6	Excessive, frequent and irregular menstruation
N93.8-N93.9	Abnormal uterine or vaginal bleeding, other specified or unspecified
N99.820-N99.821	Postprocedural hemorrhage of a genitourinary system organ or structure following a procedure
O00.0-O00.91	Ectopic pregnancy
O03.6	Delayed or excessive hemorrhage following complete or unspecified abortion
O04.6	Delayed or excessive hemorrhage following (induced) termination of pregnancy
O07.1	Delayed or excessive hemorrhage following failed attempted termination of pregnancy
O08.1	Delayed or excessive hemorrhage following ectopic and molar pregnancy
O72.0-O72.2	Postpartum hemorrhage
R10.2	Pelvic and perineal pain
R10.30-R10.32	Pain localized to other parts of lower abdomen

When services are Not Medically Necessary:

For the procedure codes listed above when criteria are not met, for the diagnosis listed below; or when the code describes a procedure or situation designated in the Clinical Indications section as not medically necessary.

ICD-10 Diagnosis	
N80.03	Adenomyosis of the uterus

Discussion/General Information

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.

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.

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:

1. Agency for Healthcare Research and Quality. Management of uterine fibroids. Comparative Effectiveness Report. 2017. Number 195. Available at: https://effectivehealthcare.ahrq.gov/topics/uterine-fibroids/research-2017. Accessed on July 13, 2023.
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History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion/General Information and References sections.

Reviewed	08/11/2022	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References section. Updated Coding section with 10/01/2022 ICD-10-CM changes; added N80.03 replacing N80.0.
Reviewed	08/12/2021	MPTAC review. Updated References section.
Reviewed	08/13/2020	MPTAC review. Updated Background/Overview, Definitions and References sections. Reformatted Coding section; updated with additional diagnosis codes.
Reviewed	08/22/2019	MPTAC review. Updated Discussion/General Information and References sections.
Reviewed	09/13/2018	MPTAC review. Updated Discussion/General Information and References sections.
Reviewed	11/02/2017	MPTAC review. Updated header language from “Current Effective Date” to “Publish Date.” Updated Discussion/General Information and References sections.
Reviewed	11/03/2016	MPTAC review. Updated Discussion/General Information, References and Coding sections.
Revised	11/05/2015	MPTAC review. Updated formatting in Criteria. Updated Discussion/General Information and References sections. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Updated Discussion/General Information and References sections.
Revised	11/14/2013	MPTAC review. Removed list of contraindications from Not Medically Necessary statement and clarified Not Medically Necessary statement. Updated Discussion/General Information, Definitions, and References. Updated Coding section with 01/01/2014 CPT changes; removed CPT 37204, 37210 deleted 12/31/2013, and 75894 (no longer applicable).
Revised	11/08/2012	MPTAC review. Added adenomyosis to Not Medically Necessary Clinical Indications. Updated Discussion/General Information and References.
Reviewed	02/16/2012	MPTAC review. Updated Discussion/General Information, Definitions, and References.
	10/01/2011	Updated Coding section with 10/01/2011 ICD-9 changes.
Reviewed	02/17/2011	MPTAC review. Updated References.
Reviewed	02/25/2010	MPTAC review. Discussion and References updated.
Reviewed	02/26/2009	MPTAC review. Place of Service removed. References updated.
Revised	02/21/2008	MPTAC review. Medically necessary criteria clarified. Discussion and References updated.
	08/03/2007	References updated.
New	03/08/2007	MPTAC review. Initial guideline development. SURG.00018 Transcatheter Uterine Artery Embolization transferred to CG-SURG- 28 Transcatheter Uterine Artery Embolization. References updated.
