

Evidence Based Guideline

Uterine Artery Occlusion in the Treatment of Uterine Fibroids

File Name: uterine_artery_occlusion_in_the_treatment_of_uterine_fibroids
Origination: 10/2000
Last CAP Review: 9/2011
Next CAP Review: 9/2012
Last Review: 9/2011

Description of Procedure or Service

Uterine leiomyomata (i.e., fibroids) are extremely common benign tumors that can be located primarily within the uterine cavity (submucosal fibroids), in the uterine wall (intramural fibroids), or on the serosal surface of the uterus (subserosal fibroids).

Two techniques have been developed that directly devascularize the uterine fibroid by interrupting the uterine arteries, and potentially serve as alternatives to hysterectomy or myomectomy. Uterine artery embolization (UAE) involves selective catheterization of the uterine arteries with injection of embolization material. More recently, laparoscopic bipolar coagulation of the uterine vessels has been investigated as an alternative to UAE.

Regulatory Status

In November 2002, Embosphere® Microspheres was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process specifically for use in uterine fibroid embolization. The FDA determined that this device was substantially equivalent to existing devices for use in arterial embolization. Since that time, several other devices such as Coutour® Emboli PVA (September 2003), Contour SE™ (March 2004), and Cook Incorporated Polyvinyl Alcohol Foam Embolization Particles (December 2008) have also received 510(k) marketing clearance for use in uterine fibroid embolization.

No devices have specific clearance/approval from the FDA for laparoscopic bipolar occlusion of the uterine vessels.

Related Policies

MRI-Guided High Intensity Ultrasound Ablation of Uterine Fibroids

*****Note: This Evidence Based Guideline is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Evidence Based Guideline for uterine artery occlusion in the treatment of uterine fibroids

Transcatheter embolization of uterine arteries may be appropriate as a treatment of uterine fibroids.

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

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- 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.

Medical Evidence regarding uterine artery occlusion in the treatment of uterine fibroids indicates it is not recommended in the following situations

Repeat transcatheter embolization of uterine arteries to treat persistent symptoms of uterine fibroids after an initial uterine artery embolization is not recommended.

Laparoscopic occlusion of the uterine arteries using bipolar coagulation is not recommended.

Rationale

The available evidence suggests that the net health outcome after one-time UAE for uterine fibroids is reasonable compared to surgery, especially for women who do not desire to maintain their fertility. There are few studies on long-term health outcomes after UAE; one series suggests that benefits are maintained for a median of 7 years. Reviews of fertility and pregnancy outcomes after UAE suggest that successful pregnancy is possible, but that there are higher rates of miscarriage and post-partum hemorrhage and higher rates of preterm delivery compared to women whose fibroids had been treated by myomectomy.

There is insufficient evidence on health outcomes associated with repeat UAE. Therefore, repeat therapy is not recommended .

There is insufficient evidence on health outcomes associated with laparoscopic occlusion of the uterine arteries. Data are lacking on outcomes compared to surgery, long-term outcomes and impact on subsequent fertility and pregnancy. Thus, laparoscopic occlusion for the treatment of uterine fibroids is not recommended.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Billing/Coding/Physician Documentation Information

This guideline may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 37210

Scientific Background and Reference Sources

From Policy Entitled: Uterine Artery Embolization to Treat Uterine Fibroids, Transcatheter Approach

TEC Assessment - 1999

BCBSA Medical Policy Reference Manual

Consultant Review 1/1999

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Medical Policy Advisory Group - 10/2000

Specialty Matched Consultant Advisory Panel - 12/2000

ECRI Windows on Medical Technology - Issue 46 - February 2001

Specialty Matched Consultant Advisory Panel - 9/2001

TEC Assessment - 2002, Tab 8

BCBSA Medical Policy Reference Manual, 4.01.11; 7/12/02

ECRI Hotline Response: Uterine Artery Embolization for Fibroids. Last updated on 3/27/03

BCBSA Medical Policy Reference Manual, 4.01.11; 7/17/03

Specialty Matched Consultant Advisory Panel - 8/2003

Policy retitled: Uterine Artery Occlusion in the Treatment of Uterine Fibroids

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.11, 11/9/04

BCBSA Technology Evaluation Center (2002, August). Uterine Artery Embolization for Treatment of Symptomatic Uterine Fibroids. Retrieved from http://www.bcbsa.com/tec/vol17/17_08.html

ECRI Hotline Response - *Uterine Artery Embolization (UAE) for Fibroids* (06/6/2005) retrieved on 6/20/05 from

http://www.ta.ecri.org/Hotline/Prod/summary/detail.aspx?doc_id+7234&q=uterine+artery&anm

National Institute for Clinical Excellence (NICE). *Guidance on Uterine artery embolisation for the treatment of fibroids*. Interventional Procedure Guidance 94. London, UK: NICE; October 2004. Available at: <http://www.nice.org.uk/pdf/ip/IPG094guidance.pdf>

Specialty Matched Consultant Advisory Panel - 8/25/05

ACOG Committee Opinion No. 293. Uterine artery embolization. *Obstet Gynecol* 2004; 103(2):403-4

American College of Obstetricians and Gynecologists. ACOG Practice Bulletin. Alternatives to hysterectomy in the management of leiomyomas. *Obstet Gynecol* 2008;112(2 pt 1):387-400

SOGC Clinical Practice Guidelines. Uterine fibroid embolization (UFE). Number 150, October 2004 *Int J Gynaecol Obstet* 2005; 89(3):305-18

BCBSA Medical Policy Reference Manual [Electronic Version] 4.01.11; 2/11/2010

BCBSA Medical Policy Reference Manual [Electronic Version] 4.01.11; 2/10/2011

Policy Implementation/Update Information

From Policy titled: Uterine Artery Embolization to Treat Uterine Fibroids, Transcatheter Approach

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|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10/00 | Medical Policy Advisory Group review. Approve. Original Policy issued. |
| 12/00 | Specialty Matched Consultant Advisory Panel review. No change to criteria. Reaffirm. |
| 6/01 | Policy changed from investigational to covered with specific indications. Format change. System coding changes. Coding format change. |
| 7/01 | Policy name changed from Transcatheter Uterine Artery Embolization to Treat Uterine Fibroids to Uterine Artery Embolization to Treat Uterine Fibroids, Transcatheter Approach. |
| 9/01 | Specialty Matched Consultant Advisory Panel review. No change in criteria. |
| 9/03 | Specialty Matched Consultant Advisory Panel review 8/4/03. "Description" and "Benefits Application" sections revised. Under "When covered" deleted #3 re: concomitant medical |

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conditions. Under "When not covered" section, added statement that repeat uterine artery embolization procedures are considered investigational. Billing/Coding section revised.

Policy retitled: Uterine Artery Occlusion in the Treatment of Uterine Fibroids

- 9/1/05 Policy name changed from "Uterine Artery Embolization to Treat Uterine Fibroids, Transcatheter Approach" to "Uterine Artery Occlusion in the Treatment of Uterine Fibroids". Under "When not covered" added "Laparoscopic occlusion of the uterine arteries using bipolar coagulation is considered investigational." Rationale for this statement placed under "Policy Guidelines". Reference sources added. Specialty Matched Consultant Advisory Panel review - 8/25/05. Following review, policy status changed to "Active policy, no longer scheduled for routine literature review". Notification given 9/1/05. Effective date 11/3/05.
- 9/18/06 Medical Policy changed to Evidence Based Guideline.
- 1/17/07 CPT code 37210 effective January 1, 2007 added to Billing/Coding section. Removed deleted CPT code S2250. (pmo)
- 9/14/10 Guideline status changed--has been returned to active review. Description section revised. Evidence Based Guideline statement changed to read: "Transcatheter embolization of uterine arteries may be appropriate as a treatment of uterine fibroids." Added the recommendation from the American College of OB/GYN regarding general criteria for treatment of fibroid tumors All other statements in this section were deleted. Everything in the Not Recommended section was deleted except for the statements regarding repeat embolization treatments and laparoscopic occlusion using bipolar coagulation. A Rationale section was added with supporting documentation. (adn)
- 1/18/11 Specialty Matched Consultant Advisory Panel review 12/16/2010. No change to guideline statement. (adn)
- 10/11/11 Description section revised. No change to medical evidence in the guideline. Rationale updated. Specialty Matched Consultant Advisory Panel review 9/28/11. (adn)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.