



MEDICAL COVERAGE GUIDELINES  
SECTION: OB/GYN/REPRODUCTION

ORIGINAL EFFECTIVE DATE: 08/21/13  
LAST REVIEW DATE: 09/18/18  
LAST CRITERIA REVISION DATE: 09/27/16  
ARCHIVE DATE:

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## LAPAROSCOPIC AND PERCUTANEOUS TECHNIQUES FOR THE MYOLYSIS OF UTERINE FIBROIDS

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Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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## **LAPAROSCOPIC AND PERCUTANEOUS TECHNIQUES FOR THE MYOLYSIS OF UTERINE FIBROIDS (cont.)**

### **Description:**

#### **Endometrium:**

The mucous membrane tissue that lines the inside of the uterus.

#### **Endometriosis:**

Abnormal occurrence of endometrial tissue growing outside the uterus in the pelvic cavity that may cause pain, irregular bleeding and/or infertility.

#### **Fibroid:**

Benign smooth muscle tumor of the uterus, also called leiomyomata. Uterine fibroids may cause pelvic pressure, pain, irregular bleeding and/or infertility.

#### **Minimally Invasive Treatments for Myolysis of Uterine Fibroids:**

Laparoscopic and percutaneous techniques using various energy sources have been investigated as minimally invasive treatments for uterine fibroids. The procedures involve multiple insertions of probes into the fibroid, and the various energy sources induce occlusion and ultimately ablation of fibroid tissue. Myolysis is most frequently performed as a laparoscopic procedure; percutaneous approaches using MRI guidance have been investigated. Energy sources for myolysis include:

- Bipolar electrodes
- Cryotherapy
- Radiofrequency ablation
- YAG lasers



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### Criteria:

For transcervical radiofrequency ablation of uterine fibroids, see BCBSAZ Medical Coverage Guideline #O969, "*Transcervical Radiofrequency Ablation of Uterine Fibroids*".

For power morcellation of the uterus, see BCBSAZ Medical Coverage Guideline #O924, "*Power Morcellation of the Uterus and Prostate*".

- The following minimally invasive treatments for myolysis of uterine fibroids are considered **experimental or investigational** based upon:
1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

Treatments include, *but are not limited to*:

- Bipolar electrodes
- Cryotherapy
- Radiofrequency ablation
- YAG lasers



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### Resources:

Literature reviewed 09/18/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 08/21/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 4.01.19 BCBS Association Medical Policy Reference Manual. Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids. Re-issue date 08/09/2018; issue date 07/15/2004.
2. Berman JM, Bolnick JM, Pemueller RR, Garza Leal JG. Reproductive Outcomes in Women Following Radiofrequency Volumetric Thermal Ablation of Symptomatic Fibroids. A Retrospective Case Series Analysis. *J Reprod Med*. May-Jun 2015;60(5-6):194-198.
3. Berman JM, Guido RS, Garza Leal JG, Pemueller RR, Whaley FS, Chudnoff SG. Three-Year Outcome of the Halt Trial: A Prospective Analysis of Radiofrequency Volumetric Thermal Ablation of Myomas. *J Minim Invasive Gynecol*. Mar 5 2014.
4. Berman JM, Puscheck EE, Diamond MP. Full-term vaginal live birth after laparoscopic radiofrequency ablation of a large, symptomatic intramural fibroid: a case report. *J Reprod Med*. Mar-Apr 2012;57(3-4):159-163.
5. Brucker SY, Hahn M, Kraemer D, Taran FA, Isaacson KB, Kramer B. Laparoscopic radiofrequency volumetric thermal ablation of fibroids versus laparoscopic myomectomy. *Int J Gynaecol Obstet*. Jun 2014;125(3):261-265.
6. Chudnoff SG, Berman JM, Levine DJ, Harris M, Guido RS, Banks E. Outpatient procedure for the treatment and relief of symptomatic uterine myomas. *Obstet Gynecol*. May 2013;121(5):1075-1082.
7. Galen DI, Isaacson KB, Lee BB. Does menstrual bleeding decrease after ablation of intramural myomas? A retrospective study. *J Minim Invasive Gynecol*. Nov-Dec 2013;20(6):830-835.
8. Galen DI, Pemueller RR, Leal JG, Abbott KR, Falls JL, Macer J. Laparoscopic radiofrequency fibroid ablation: phase II and phase III results. *JSLs*. Apr-Jun 2014;18(2):182-190.



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### Resources: (cont.)

9. Guido RS, Macer JA, Abbott K, Falls JL, Tilley IB, Chudnoff SG. Radiofrequency volumetric thermal ablation of fibroids: a prospective, clinical analysis of two years' outcome from the Halt trial. *Health Qual Life Outcomes*. 2013;11:139.
10. Hahn M, Brucker S, Kraemer D, et al. Radiofrequency Volumetric Thermal Ablation of Fibroids and Laparoscopic Myomectomy: Long-Term Follow-up From a Randomized Trial. *Geburtshilfe Frauenheilkd*. May 2015;75(5):442-449.
11. Lee BB, Isaacson KB, Diamond MP, Halt Medical I, al e. Radiofrequency Volumetric Thermal Ablation of Symptomatic Uterine Fibroids: The Acessa Procedure. *Leiomyomas: Risk Factors, Clinical Manifestations and Treatment Options*. 2015;Chapter 9:175-194.
12. Robles R, Aguirre VA, Argueta AI, Guerrero MR. Laparoscopic radiofrequency volumetric thermal ablation of uterine myomas with 12 months of follow-up. *Int J Gynaecol Obstet*. Jan 2013;120(1):65-69.



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### Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, [crc@azblue.com](mailto:crc@azblue.com). You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

### Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Dii kwe'é atah nilinigií Blue Cross Blue Shield of Arizona haada yit'éego bina'idilkidgo éi doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idilkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í' hodilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

### Arabic:

إن كان لديك أو لدى شخص تساعدك أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

