



MEDICAL COVERAGE GUIDELINES  
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 09/16/14  
LAST REVIEW DATE: 09/18/18  
LAST CRITERIA REVISION DATE: 09/26/17  
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## POWER MORCELLATION OF THE UTERUS AND PROSTATE

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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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## POWER MORCELLATION OF THE UTERUS AND PROSTATE (cont.)

### Description:

Morcellation is the division of tissue into smaller pieces or fragments to facilitate removal of tissue. Laparoscopic power morcellators (LPMs) are medical devices used to fragment tissue to allow surgical specimens to be removed through small incisions during minimally invasive laparoscopic surgeries including uterine and prostate surgeries.

The FDA issued a safety communication 04/17/2014 discouraging the use of laparoscopic power morcellation during hysterectomy or myomectomy for the treatment of women with uterine fibroids. Per the safety communication, in women with unsuspected uterine sarcoma, the procedure could spread cancerous tissue within the abdomen and pelvis significantly worsening likelihood of long-term survival. The FDA updated its recommendation to include a boxed warning on the product labeling 11/24/2014.

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### Criteria:

**For laser prostatectomy surgery, see BCBSAZ Medical Coverage Guideline, #O1017, “*Laser Prostatectomy*”.**

**For laparoscopic and percutaneous techniques for myolysis of uterine fibroids, see BCBSAZ Medical Coverage Guideline #O807, “*Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids*”.**

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

- Laparoscopic power morcellation in the treatment of uterine disorders is 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.

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## **POWER MORCELLATION OF THE UTERUS AND PROSTATE (cont.)**

### **Criteria: (cont.)**

- Laparoscopic power morcellation of prostate as a stand-alone treatment of benign prostatic hypertrophy is 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.

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### **Resources:**

**Literature reviewed 09/26/17. We do not include marketing materials, poster boards and non-published literature in our review.**

**Resources prior to 09/27/16 may be requested from the BCBSAZ Medical Policy and Technology Research Department.**

1. Alfaro-Alfaro J, Flores-Manzur Mde L, Nevarez-Bernal R, Ayala-Yanez R. Complex Laparoscopic Myomectomy with Severe Adhesions Performed with Proper Preventive Measures and Power Morcellation Provides a Safe Choice in Certain Infertility Cases. *Case reports in obstetrics and gynecology*. 2016;2016:4705790.
2. Anapolski M, Panayotopoulos D, Alkatout I, et al. Power morcellation inside a secure endobag: a pilot study. *Minimally invasive therapy & allied technologies : MITAT : official journal of the Society for Minimally Invasive Therapy*. Aug 2016;25(4):203-209.
3. Aoki Y, Matsuura M, Matsuno T, Yamamoto T. Single-site in-bag morcellation achieved via direct puncture of the pneumoperitoneum cap, a cordless electric morcellator, and a 5-mm flexible scope. *European journal of obstetrics, gynecology, and reproductive biology*. Jun 2016;201:126-130.
4. Boruta DM, Shibley T. Power Morcellation of Unsuspected High-grade Leiomyosarcoma Within an Inflated Containment Bag: 2-year Follow-up. *J Minim Invasive Gynecol*. Sep-Oct 2016;23(6):1009-1011.
5. Brolmann HA, Sizzi O, Hehenkamp WJ, Rossetti A. Laparoscopic power morcellation of presumed fibroids. *Minerva ginecologica*. Jun 2016;68(3):352-363.

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## **POWER MORCELLATION OF THE UTERUS AND PROSTATE (cont.)**

### **Resources:** (cont.)

6. Cohen SL, Morris SN, Brown DN, et al. Contained tissue extraction using power morcellation: prospective evaluation of leakage parameters. *Am J Obstet Gynecol.* Feb 2016;214(2):257.e251-256.
7. Gerges B, Mongelli M, Casikar I, Bignardi T, Condous G. 3D transvaginal sonography as pre-operative predictor of the need to morcellate in women undergoing laparoscopic hysterectomy. *Ultrasound in obstetrics & gynecology : the official journal of the International Society of Ultrasound in Obstetrics and Gynecology.* Jun 9 2016.
8. Harris JA, Swenson CW, Uppal S, et al. Practice patterns and postoperative complications before and after US Food and Drug Administration safety communication on power morcellation. *Am J Obstet Gynecol.* Jan 2016;214(1):98.e91-98.e13.
9. Ikhen DE, Paintal A, Milad MP. Feasibility of Washings at the Time of Laparoscopic Power Morcellation: A Pilot Study. *J Minim Invasive Gynecol.* Jul-Aug 2016;23(5):793-797.
10. Istre O. Unexpected Uterine Leiomyosarcoma During Laparoscopic Hysterectomy Treated 6 Months With Ulipristal Acetate and Contained Power Morcellation. *J Minim Invasive Gynecol.* Aug 15 2016.
11. Kerbage Y, Azais H, Estevez JP, Merlot B, Collinet P. [Current controversies regarding power morcellation and future directions]. *Gynecologie, obstetrique & fertilite.* Jul-Aug 2016;44(7-8):417-423.
12. Krentel H, De Wilde RL. Complications in Laparoscopic Supracervical Hysterectomy(LASH), especially the morcellation related. *Best practice & research. Clinical obstetrics & gynaecology.* Aug 2016;35:44-50.
13. Leal MA, Pinera A, De Santiago J, Zapardiel I. Novel Technique for Contained Power Morcellation through Umbilicus with Insufflated Bag. *Gynecologic and obstetric investigation.* 2017;82(2):205-207.
14. Lete I, Gonzalez J, Ugarte L, Barbadillo N, Lapuente O, Alvarez-Sala J. Parasitic leiomyomas: a systematic review. *European journal of obstetrics, gynecology, and reproductive biology.* Aug 2016;203:250-259.
15. Lu B, Xu J, Pan Z. Iatrogenic parasitic leiomyoma and leiomyomatosis peritonealis disseminata following uterine morcellation. *The journal of obstetrics and gynaecology research.* Aug 2016;42(8):990-999.



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### Resources: (cont.)

16. Paul PG, Thomas M, Das T, Patil S, Garg R. Contained Morcellation for Laparoscopic Myomectomy Within a Specially Designed Bag. *J Minim Invasive Gynecol*. Feb 1 2016;23(2):257-260.
17. Perkins RB, Handal-Orefice R, Hanchate AD, Lin M, Paasche-Orlow MK. Risk of Undetected Cancer at the Time of Laparoscopic Supracervical Hysterectomy and Laparoscopic Myomectomy: Implications for the Use of Power Morcellation. *Women's health issues : official publication of the Jacobs Institute of Women's Health*. Jan-Feb 2016;26(1):21-26.
18. Rechberger T, Miotla P, Futyma K, et al. Power morcellation for women undergoing laparoscopic supracervical hysterectomy - safety of procedure and clinical experience from 426 cases. *Ginekologia polska*. 2016;87(8):546-551.
19. Rimbach S, Holzknacht A, Schmedler C, Nemes C, Offner F. First clinical experiences using a new in-bag morcellation system during laparoscopic hysterectomy. *Archives of gynecology and obstetrics*. Jul 2016;294(1):83-93.
20. Skorstad M, Kent A, Lieng M. Uterine leiomyosarcoma - incidence, treatment, and the impact of morcellation. A nationwide cohort study. *Acta obstetrica et gynecologica Scandinavica*. Sep 2016;95(9):984-990.
21. Smits RM, De Kruijff JH, Van Heteren CF. Complication rate of uterine morcellation in laparoscopic supracervical hysterectomy: a retrospective cohort study. *European journal of obstetrics, gynecology, and reproductive biology*. Apr 2016;199:179-182.
22. Toubia T, Moulder JK, Schiff LD, Clarke-Pearson D, O'Connor SM, Siedhoff MT. Peritoneal Washings After Power Morcellation in Laparoscopic Myomectomy: A Pilot Study. *J Minim Invasive Gynecol*. May-Jun 2016;23(4):578-581.
23. Up to Date. Laparoscopic Hysterectomy. Last updated 03/28/2016, 10/01/2014, 08/18/2014.
24. Up to Date. Differentiating Uterine Leiomyomas (Fibroids) From Uterine Sarcomas. Last updated 01/04/2017, 04/21/2015, 08/19/2014.
25. Up to Date. Instruments and Devices Used in Laparoscopic Surgery. Last updated 08/15/2017, 08/04/2014.
26. UpToDate.com. Uterine tissue extraction by morcellation: Techniques and clinical issues. 08/07/2017, 08/08/2016.



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## POWER MORCELLATION OF THE UTERUS AND PROSTATE (cont.)

### Resources: (cont.)

27. Vallabh-Patel V, Saiz C, Salamon C, Francis A, Pagnillo J, Culligan P. Prevalence of Occult Malignancy Within Morcellated Specimens Removed During Laparoscopic Sacrocolpopexy. *Female pelvic medicine & reconstructive surgery*. Jul-Aug 2016;22(4):190-193.
28. Venturella R, Rocca ML, Lico D, et al. In-bag manual versus uncontained power morcellation for laparoscopic myomectomy: randomized controlled trial. *Fertil Steril*. May 2016;105(5):1369-1376.
29. Zhang J, Li T, Zhang J, Zhu L, Lang J, Leng J. Clinical Characteristics and Prognosis of Unexpected Uterine Sarcoma After Hysterectomy for Presumed Myoma With and Without Transvaginal Scalpel Morcellation. *International journal of gynecological cancer : official journal of the International Gynecological Cancer Society*. Mar 2016;26(3):456-463.



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## POWER MORCELLATION OF THE UTERUS AND PROSTATE (cont.)

### 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: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idíílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíílkidgo beehaz'áanii hólg díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 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 تساعد 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.

