

BSC7.06	Power Morcellation for the Treatment of Uterine Fibroids		
Original Policy Date:	November 26, 2014	Effective Date:	June 1, 2023
Section:	7.0 Surgery	Page:	Page 1 of 10

Policy Statement

- I. Laparoscopic power morcellation in hysterectomy and myomectomy is considered **investigational** for the treatment of uterine fibroids.

NOTE: Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Laparoscopic uterine power morcellation may be billed using the following CPT codes:

- **58578:** Unlisted laparoscopy procedure, uterus
- **58999:** Unlisted procedure, female genital system (nonobstetrical)

The above CPT codes may come along with the primary procedure CPT codes for laparoscopic hysterectomy or myomectomy (58545-58554).

Description

Power morcellation refers to the dissection of tissue by an electromechanical device into pieces or fragments small enough to be removed during a laparoscopic procedure. In gynecologic surgery, power morcellation may be used to treat uterine fibroids during a hysterectomy (removal of the entire uterus) or myomectomy (removal of uterine fibroids). The use of laparoscopic power morcellation to treat uterine fibroids has the potential risk of intraperitoneal spread of undiagnosed endometrial carcinoma or leiomyosarcoma.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

The U.S. Food and Drug Administration (FDA) issued a safety communication on April 17, 2014¹ and updated November 24, 2014² regarding laparoscopic uterine power morcellation in hysterectomy and myomectomy. The following is a portion of the statement provided by the FDA:

"Purpose:

When used for hysterectomy or myomectomy in women with uterine fibroids, laparoscopic power morcellation poses a risk of spreading unsuspected cancerous tissue, notably uterine sarcomas, beyond the uterus. The FDA is warning against using laparoscopic power morcellators in the majority of women undergoing hysterectomy or myomectomy for uterine fibroids. Health care providers and patients should carefully consider available alternative treatment options for the removal of symptomatic uterine fibroids.

Summary of Problem and Scope:

...Based on an FDA analysis of currently available data, we estimate that approximately 1 in 350 women undergoing hysterectomy or myomectomy for the treatment of fibroids is found to have an unsuspected uterine sarcoma, a type of uterine cancer that includes leiomyosarcoma. At this time, there is no reliable method for predicting or testing whether a woman with fibroids may have a uterine sarcoma.

If laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma, there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient's long-term survival. While the specific estimate of this risk may not be known with certainty, the FDA believes that the risk is higher than previously understood.

Because of this risk and the availability of alternative surgical options for most women, **the FDA is warning against the use of laparoscopic power morcellators in the majority of women undergoing myomectomy or hysterectomy for treatment of fibroids.**

Limiting the patients for whom laparoscopic morcellators are indicated, the strong warning on the risk of spreading unsuspected cancer, and the recommendation that doctors share this information directly with their patients, are part of FDA guidance to manufacturers of morcellators. The guidance strongly urges these manufacturers to include this new information in their product labels.

Recommendations for Health Care Providers:

- Be aware of the following new contraindications recommended by the FDA;
 - Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are peri- or post-menopausal, or are candidates for en bloc tissue removal, for example through the vagina or mini-laparotomy incision. (Note: These groups of women represent the majority of women with fibroids who undergo hysterectomy and myomectomy.)
 - Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.
- Be aware of the following new boxed warning recommended by the FDA:
The FDA warns that uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.
- Carefully consider all the available treatment options for women with uterine fibroids.
- Thoroughly discuss the benefits and risks of all treatments with patients. Be certain to inform the small group of patients for whom laparoscopic power morcellation may be an acceptable therapeutic option that their fibroid(s) may contain unexpected cancerous tissue and that laparoscopic power morcellation may spread the cancer, significantly worsening their prognosis. This population might include some younger women who want to maintain their

fertility or women not yet peri-menopausal who wish to keep their uterus after being informed of the risks.”

In 2017, the FDA updated their assessment of the use of laparoscopic power morcellators to treat uterine fibroids.³ The FDA’s Center for Devices and Radiological Health (CDRH) concluded:

“While minimally invasive surgery conveys several significant advantages over open surgery for women with fibroids, the use of LPMs during these surgeries poses a risk due to the potential presence of unsuspected sarcoma in this population. FDA continues to caution against the use of LPMs in the majority of women undergoing myomectomy or hysterectomy for treatment of fibroids. The Agency also continues to recommend that the advantages and risks of using LPMs during fibroid surgery be thoroughly discussed between the patient and physician before surgery. FDA continues to actively encourage and engage in research to evaluate outcomes for a range of treatment options for fibroids and support the development of safer alternatives for providing a minimally invasive approach.”

The FDA prepared an executive summary for the July 10-11, 2014 meeting of the Obstetrics and Gynecology Devices Advisory Committee on Laparoscopic Power Morcellation during Uterine Surgery for Fibroids.⁴ The following are the key points based on the FDA’s analysis and review of the literature to date:

1. “The risk of having an unsuspected sarcoma in the population of women undergoing hysterectomy or myomectomy for presumed fibroids may be as high as approximately 1 in 350 for all types of uterine sarcomas, and 1 in 500 for LMS specifically.”
2. “Peritoneal dissemination and/or cancer upstaging (to FIGO Stage III or IV) following morcellation of an unsuspected sarcoma may occur in approximately 25-65% of cases.”
3. “Patients with unsuspected uterine sarcoma who undergo morcellation may be at significantly higher risk for local (pelvic/abdominal) and overall cancer recurrence compared to those who do not undergo morcellation.”
4. “Patients with unsuspected sarcoma who undergo morcellation may have poorer disease-free survival and overall survival compared to patients who do not receive morcellation.”

Limitations to the FDA review are the following:

- “...although an attempt was made to survey the literature regarding the risk of morcellating an occult uterine sarcoma, the available literature was primarily focused on LMS.”
- Since it is “based on a review of the published literature, primarily of patients seen at large clinical centers, the analysis is limited by potential publication, selection, and referral bias. To control for selection bias, the analysis of the prevalence of unsuspected sarcoma was limited to only those studies that included patients undergoing hysterectomy or myomectomy for presumed benign leiomyomas and did not include a more general patient population undergoing other gynecologic procedures. To control for differences across studies, random-effects modeling was employed for prevalence estimates.”
- “...there are some cases in which scalpel morcellation was used and other cases where it was not specified.”
- “...the analysis is based on a relatively small number of studies, many of which included a small number of patients and statistical significance was not reached for some outcomes comparing morcellated to non-morcellated patients. In addition, the studies were not randomized so it is possible there were differences between morcellated and non-morcellated patients.”

In regards to the use of an extraction bag during morcellation, the FDA noted that only one study (George et al, 2014⁵) excluded patients whose procedure used extraction bags, while other studies did not comment on their use. The FDA found that despite the above noted limitations, there is

consistency among the findings in many studies, suggesting when an unsuspected sarcoma is morcellated, it leads to a poorer prognosis.

Rationale

Background

Uterine fibroid tumors (i.e., leiomyomas) are the most common type of female reproductive tract tumor and may be associated with menorrhagia, pelvic pressure/pain, infertility, and pregnancy loss. The treatment for fibroids has a range of options, including but not limited to medical management of symptoms, uterine artery embolization, ablative procedures, and surgery. According to the American Cancer Society uterine sarcomas represent <5% of uterine cancers and it is estimated that in the United States for 2019 about 61,880 new cases of cancer of the uterine corpus (body of the uterus) will be diagnosed.⁶ The prognosis for uterine sarcomas tend to be worse than other uterine cancers due to the fact that they are often more aggressive and are diagnosed after they reach an advanced stage.

Surgical treatment of uterine fibroids is often by hysterectomy or myomectomy. These procedures are now more commonly done as minimally invasive laparoscopic procedures versus an open procedure. Laparoscopic procedures are associated with shorter hospital stays and lower risks of infections, but do carry the risk of longer operating times and the need for morcellation.

Morcellation refers to the division of tissue into smaller pieces in order to be removed from a small incision as during minimally invasive laparoscopic procedures. Manual morcellation (by use of scalpels, forceps, clamps) has been in practice for several decades; however power morcellation (by use of an electromechanical device) was introduced in the early 1990's. The introduction of power morcellation allowed for a faster removal time of tissue. Steiner et al (1993) described the new power morcellator as a "cylinder with a coning knife at its intra-abdominal end...and is rotated by an electrical micro-engine attached to the trocar."⁷ Driessen et al (2014) conducted a literature review to assess all electromechanical morcellators used in gynecology.⁸ The authors found that the devices ranged in the morcellation rate from 6.2 g/min to 40.4 g/min and concluded that limitations (tissue scattering, morcellator-related injuries, small blade diameter) still remained.

Though most cases of uterine fibroids are benign, there is the risk that there may be an unsuspected uterine sarcoma. When power morcellation is used during a hysterectomy or a myomectomy for the treatment of uterine fibroids, the risk of intraperitoneal dissemination of unsuspected malignant tissue is a concern. The dissemination may result in the upstaging of a tumor and worsen a patient's long-term survival rate.

Literature Review

Wright et al (2014) published a research letter investigating the prevalence of underlying cancer in women who underwent uterine morcellation.⁹ The authors identified 232,882 women who underwent minimally invasive hysterectomies from 2006-2012. Among those women, they found 36,470 who had morcellation performed during the procedure. The analysis demonstrated that uterine cancers occurred in 27 per 10,000 women who underwent morcellation and noted that women with suspected neoplasms confined to the uterus at the time morcellation was performed, were found to have intraperitoneal tumor dissemination during reexploration procedures. The authors acknowledged the limitations to the study and emphasized the importance of adequate counseling about the prevalence of cancerous and precancerous conditions prior to undergoing a procedure involving morcellation.

Bogani et al (2015)¹⁰, conducted a systematic review and meta-analysis on the effects of intra-abdominal morcellation on survival outcomes of patients affected by unexpected uterine leiomyosarcoma. Four manuscripts involving 202 patients were included: 75 patients had

morcellation of unexpected uterine leiomyosarcoma; 127 patients did not. The authors concluded that there is a significant correlation between uterine morcellation and an increased risk of intra-abdominal recurrence in patients affected by unexpected uterine leiomyosarcoma. It was determined that further studies are needed due to the limited amount of evidence on this issue.

Summary of Evidence

Power morcellation poses the potential risk of intraperitoneal spread of undiagnosed endometrial carcinoma or leiomyosarcoma. In April 2014 (updated November 2014), the FDA issued a safety warning for laparoscopic uterine power morcellation which in turn has greatly suspended the use of these devices in several U.S. hospitals. After the safety warning was issued, numerous national societies issued position statements regarding the potential risks of power morcellation. Therefore, due to the safety concerns of this procedure, power morcellation in hysterectomy and myomectomy for the treatment of uterine fibroids is considered investigational.

Supplemental Information Practice Guidelines and Position Statements

American College of Obstetricians and Gynecologists (ACOG)

According to a report published in May 2014 discussing power morcellation and occult malignancy in gynecologic surgery, ACOG states, "In women with strongly suspected or known malignancy, power morcellation should not be used."¹¹ The report goes on to discuss the importance of patient counseling and informed consent. Due to the risks involved with this procedure, ACOG recommends the following guidelines during the informed consent process when power morcellation is being considered:

- "There is a potential risk of undiagnosed gynecologic cancers. The precise incidence of all undiagnosed uterine sarcomas – including leiomyosarcoma – in women undergoing hysterectomy for fibroids is unknown. However, the risk estimate of approximately 2:1000 women who undergo hysterectomy or myomectomy should be discussed."
- "If an occult malignancy is present, the use of power morcellation will increase the likelihood of intraperitoneal dissemination. It also may worsen the patient's prognosis, make a definitive diagnosis (histologic interpretation) and accurate staging of an underlying malignancy more difficult, and result in the need for additional surgery, medical management, or both."
- "If fragments of benign tissue are disseminated through morcellation, there is the possibility of seeding viable ectopic tissue as a result (e.g., leiomyoma, endometriosis, adenomyosis, and ovarian remnants). This potentially may require additional intervention."
- "If power morcellation is to include the use of an intraperitoneal bag, potential concerns should be discussed, including insufficient bag size, disruption of the bag by the morcellator, and reduced visualization as a result of using the bag."
- "Alternatives to the use of power morcellation should be discussed, including removal of intact tissue through mini-laparotomy, laparotomy, or colpotomy incisions, or by total abdominal hysterectomy, vaginal hysterectomy, or laparoscopic vaginal hysterectomy."

Society of Gynecologic Oncology (SGO)

In December 2013, the SGO published a position statement on morcellation which stated the following:¹²

"... power morcellation or other techniques that cut up the uterus in the abdomen have the potential to disseminate an otherwise contained malignancy throughout the abdominal cavity. For this reason, the Society of Gynecologic Oncology (SGO) asserts that it is generally contraindicated in the presence of documented or highly suspected

malignancy, and may be inadvisable in premalignant conditions or risk-reducing surgery.”

National Comprehensive Cancer Network (NCCN)

According to the NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms (Version 1.2023)¹³, the following was recommended:

- “Endometrial carcinoma should be removed en bloc to optimize outcomes; intraperitoneal morcellation or tumor fragmentation should be avoided.”
- “Uterine sarcoma should be removed *en bloc* to optimize outcomes; morcellation should be avoided.”

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

References

1. U.S. Food and Drug Administration (FDA). Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication. April 2014. <https://wayback.archive-it.org/7993/20170406071822/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm393576.htm>. Accessed April 27, 2023.
2. U.S. Food and Drug Administration (FDA). Updated Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication. November 2014. <https://wayback.archive-it.org/7993/20170404182209/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm424443.htm>. Accessed April 27, 2023.
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4. U.S. Food and Drug Administration (FDA). FDA Executive Summary: Laparoscopic Power Morcellation during Uterine Surgery for Fibroids. 2014. https://injuryrecoveryinstitute.com/wp-content/uploads/2014/09/Laparoscopic-PowerMorcellation-during-Uterine-Surgery-for-Fibroids_FDA.pdf. Accessed January 24, 2019.
5. George S, Barysaukas C, Serrano C. Retrospective cohort study evaluating the impact of intraperitoneal morcellation on outcomes of localized uterine leiomyosarcoma. *Cancer*. 2014; 120(20):3154-3158.
6. American Cancer Society. About Uterine Sarcoma. 2023. <https://www.cancer.org/cancer/uterine-sarcoma/about.html>. Accessed April 27, 2023.
7. Steiner RA, Wight E, Tadir Y et al. Electrical cutting device for laparoscopic removal of tissue from the abdominal cavity. *Obstet Gynecol*. 1993; 81(3):471.
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10. Bogani G, Cliby WA, Aletti GD. Impact of morcellation on survival outcomes of patients with unexpected uterine leiomyosarcoma: A systematic review and meta-analysis. *Gynecologic Oncology*. 2015;137(1):167-172.

11. American College of Obstetricians and Gynecologists. Power Morcellation and Occult Malignancy in Gynecologic Surgery: A Special Report*. 2014. <https://www.acog.org/Clinical-Guidance-and-Publications/Task-Force-and-Work-GroupReports/Power-Morcellation-and-Occult-Malignancy-in-Gynecologic-Surgery>. Accessed January 24, 2019.
12. Society of Gynecologic Oncology. SGO Position Statement: Morcellation. 2013. <https://www.sgo.org/newsroom/position-statements-2/morcellation/>. Accessed April 27, 2023.
13. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms (Version 1.2023). December 22, 2022. https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed April 27, 2023.
14. U.S. Food and Drug Administration (FDA). Laparoscopic Power Morcellators. Final Guidance: Product Labeling for Laparoscopic Power Morcellators. 2020. <https://www.fda.gov/medical-devices/surgery-devices/laparoscopic-power-morcellators>. Accessed April 27, 2023.
15. U.S. Food and Drug Administration (FDA). Product Labeling for Laparoscopic Power Morcellators. Guidance for Industry and Food and Drug Administration Staff. 2020. <https://www.fda.gov/media/90012/download>. Accessed April 27, 2023.

Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	58545	Laparoscopy, surgical, myomectomy, excision; 1 to 4 intramural myomas with total weight of 250 g or less and/or removal of surface myomas
	58546	Laparoscopy, surgical, myomectomy, excision; 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g
	58548	Laparoscopy, surgical, with radical hysterectomy, with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy), with removal of tube(s) and ovary(s), if performed
	58550	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less
	58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
	58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g;
	58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
	58578	Unlisted laparoscopy procedure, uterus
	58999	Unlisted procedure, female genital system (nonobstetrical)

Type	Code	Description
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
11/26/2014	Custom policy
05/01/2016	Policy revision without position change
05/01/2017	Policy revision without position change
05/01/2018	Policy revision without position change
03/01/2019	Policy revision without position change
05/01/2020	Annual review. No change to policy statement. Literature review updated.
05/01/2021	Annual review. No change to policy statement.
06/01/2022	Annual review. No change to policy statement. Literature review updated.
06/01/2023	Annual review. No change to policy statement.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	AFTER <u>Blue font: Verbiage Changes/Additions</u>
<p>Power Morcellation for the Treatment of Uterine Fibroids BSC7.06</p> <p>Policy Statement: Laparoscopic power morcellation in hysterectomy and myomectomy is considered investigational for the treatment of uterine fibroids.</p>	<p>Power Morcellation for the Treatment of Uterine Fibroids BSC7.06</p> <p>Policy Statement:</p> <ul style="list-style-type: none"> I. Laparoscopic power morcellation in hysterectomy and myomectomy is considered investigational for the treatment of uterine fibroids.