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.

Policy

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

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).

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)) prohibit 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.
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 2014 about 52,630 new cases of cancer of the uterine corpus (body of the uterus) will be diagnosed with only 1,600 of these cases being uterine sarcomas. (1) 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.” (2) Driessen et al. (2014) conducted a literature review to assess all electromechanical morcellators used in gynecology. (3) 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 and Position Statements

U.S. Food and Drug Administration (FDA)

The FDA issued a safety communication on April 17, 2014 regarding laparoscopic uterine power morcellation in hysterectomy and myomectomy. (4) 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. Health care providers and patients should carefully consider available alternative treatment options for symptomatic uterine fibroids. Based on currently available information, the FDA discourages the use of
laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids.

Summary of Problem and Scope:

...Importantly, based on an FDA analysis of currently available data, it is estimated that 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. 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 likelihood of long-term survival. For this reason, and because there is no reliable method for predicting whether a woman with fibroids may have a uterine sarcoma, the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids.

Recommendations for Health Care Providers:

- Be aware that based on currently available information, the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for the treatment of women with uterine fibroids.
- Do not use laparoscopic uterine power morcellation in women with suspected or known uterine cancer.
- Carefully consider all the available treatment options for women with symptomatic uterine fibroids.
- Thoroughly discuss the benefits and risks of all treatments with patients.
- For individual patients for whom, after a careful benefit-risk evaluation, laparoscopic power morcellation is considered the best therapeutic option:
  - Inform patients that their fibroid(s) may contain unexpected cancerous tissue and that laparoscopic power morcellation may spread the cancer, significantly worsening their prognosis.
  - Be aware that some clinicians and medical institutions now advocate using a specimen “bag” during morcellation in an attempt to contain the uterine tissue and minimize the risk of spread in the abdomen and pelvis.

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.(5) 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 24 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 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.

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.”(7) 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:(8)

... 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 1.2015), “endometrial carcinoma should be removed en bloc to optimize outcomes; morcellation should be avoided.”(9)

Journal of the American Medical Association

Wright et al. (2014) published a research letter investigating the prevalence of underlying cancer in women who underwent uterine morcellation.(10) 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.

**Summary**

Power morcellation poses the potential risk of intraperitoneal spread of undiagnosed endometrial carcinoma or leiomyosarcoma. In April 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.

**References**

Documentation Required for Clinical Review

- History and physical and/or consultation notes including:
  - Procedure being performed (e.g., laparoscopic hysterectomy/myomectomy)
  - Reason for procedure

Post Service
- Operative report

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

IE

The following services are considered investigational and therefore not covered for any indication.

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<th>Type</th>
<th>Code</th>
<th>Description</th>
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<td>58545</td>
<td>Laparoscopy, surgical, myomectomy, excision; 1 to 4 intramural myomas with total weight of 250 g or less and/or removal of surface myomas</td>
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<td>58546</td>
<td>Laparoscopy, surgical, myomectomy, excision; 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g</td>
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<td>58548</td>
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<td>58999</td>
<td>Unlisted procedure, female genital system (nonobstetrical)</td>
</tr>
</tbody>
</table>

HCPC  None

ICD-9 Procedure None
Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

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

This service (or procedure) is considered medically necessary in certain instances and investigational in others (refer to policy for details).

For instances when the indication is medically necessary, clinical evidence is required to determine medical necessity.

For instances when the indication is investigational, you may submit additional information to the Prior Authorization Department.

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 also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.