Clinical Policy Title: Leiomyosarcoma and laparoscopic power morcellation

Clinical Policy Number: CCP.1130

Effective Date: January 1, 2015
Initial Review Date: August 20, 2014
Most Recent Review Date: August 1, 2018
Next Review Date: August 2019

Related policies:
None.

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of laparoscopic power morcellation to be investigational/experimental and, therefore, not medically necessary.

Limitations:
None.

Alternative covered services:

- Surgical hysterectomy and myomectomy.
- Laparoscopic hysterectomy and myomectomy without morcellation.
- Laparotomy using a smaller incision (minilaparotomy).
- Deliberate blocking of the uterine artery (catheter-based uterine artery embolization).
- High-intensity focused ultrasound.
- Drug therapy.
Background

Uterine sarcomas are a rare form of uterine cancer, accounting for three to five percent of all uterine cancers diagnosed in the United States. Uterine sarcomas occur in the myometrium or connective tissue of the uterus and are highly aggressive. Leiomyosarcomas are a rare form of soft-tissue cancer that is often dormant, but can be fatal after diagnosis. They can be found in multiple sites, often in the uterus and gastrointestinal system. The five-year survival rate for leiomyosarcoma is 63, 36, and 14 percent for localized, regional, and distant, respectively (American Cancer Society, 2017).

Laparoscopic power morcellation, introduced in 1993, is a U.S. Food and Drug Administration-approved, minimally invasive technique used in gynecological surgery. Among its uses is the treatment of uterine fibroids. Morcellation devices are electrical surgical implements resembling a drill with sharp blades that cut tissue into smaller fragments to facilitate vacuum removal of tissue through small incisions. Power morcellation products include Gynecare Morcellex, Morce Power Plus, Variocarve, and PKS Plasma.

Spurred by reports on unexpectedly high complication rates began to emerge (Milad, 2014), recent clinical information suggests laparoscopic power morcellation poses a risk of spreading unsuspected cancerous tissue, such as uterine sarcomas, beyond the uterus. On April 17, 2014, the Food and Drug Administration withdrew approval of laparoscopic power morcellators because of this risk (U.S. Food and Drug Administration, 2014b).

Although many women develop uterine fibroids in their lifetimes, most fibroids cause no symptoms. Some cases result in heavy or prolonged menstrual bleeding, pelvic pressure or pain, or frequent urination. It is estimated that one 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. Since no reliable method exists to predict whether a woman’s uterine fibroid may have sarcoma, and with the risk of spreading possible cancerous tissue within the abdomen and pelvis, laparoscopic power morcellation is discouraged by the Food and Drug Administration.

Johnson & Johnson suspended sales of Gynecare Morcellex in April 2014 and asked customers to return morcellators, with the possibility of bringing them back in the future. On July 30, 2014, Ethicon Inc. (a manufacturer of Gynecare Morcellex and a subsidiary of Johnson & Johnson) instituted a recall on all its morcellation devices, citing uncertainty in the risk-benefit assessment associated with the use of power morcellators (Ethicon, 2014). On November 24, 2014, the Food and Drug Administration issued an updated warning on laparoscopic power morcellators, against using these devices for women with uterine fibroids who are not suspected to have cancer and are undergoing hysterectomy or myomectomy. The Food and Drug Administration also advised physicians to discuss the risk with patients and urged manufacturers to include warnings on product labels (U.S. Food and Drug Administration, 2014b).

In December 2017, the Food and Drug Administration issued a release, acknowledging numerous
correspondence from health professionals, contending that the risk of laparoscopic power morcellation was lower than in the 2014 warning. The Administration responded by stating a review of all subsequent evidence upheld the accuracy of the degree of risk from 2014 (U.S. Food and Drug Administration, 2017). On February 16, 2018, the Food and Drug Administration followed with a description of morcellators, their risks, and ways to reduce risk (U.S. Food and Drug Administration, 2018).

As of March 2016, at least 31 law suits by women contending the use of morcellators had been brought, and are pending in federal court. In the spring of 2018, Johnson & Johnson began to settle the suits (Llamas, 2018).

Following the initial Food and Drug Administration warning, the National Institute for Health and Care Excellence issued a guideline in June 2015, stating current evidence on hysteroscopic morcellation for uterine fibroids is limited, and thus should be conducted only “with special arrangements for clinical governance, consent, and audit or research (National Institute for Health and Care Excellence, 2015). The American College of Obstetricians and Gynecologists produced a special report calling for more research into developing reliable tools that can diagnose uterine malignancies prior to surgery, and to develop safer methods of reducing risk of tissue dissemination (American College of Obstetricians and Gynecologists, 2014).

Searches

Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on June 7, 2018. Search terms were: “leiomyosarcoma,” “morcellation,” and “uterine fibroids.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews**.

- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.
Findings

Research on the use of power morcellation in women with uterine fibroids continued even after the Food and Drug Administration issued its warning. A study of 34,728 women enrolled in the Kaiser-Permanente health plan undergoing hysterectomy for leiomyoma from 2006 to 2013 found an elevated one-year death rate for those in whom sarcomas were detected; the three-year death rate failed to achieve statistical significance (Raine-Bennett, 2016).

Another recent report documented a lower rate of disease-free survival in women with malignancies after minimally invasive hysterectomy (Graebe, 2015). A systematic review and meta-analysis of four articles (n = 202) compared leiomyosarcoma patients who were or were not treated with morcellation. Those treated with morcellation had a higher overall (62 versus 39 percent) and intra-abdominal (39 versus nine percent) recurrence rate, and a higher (48 versus 29 percent) death rate (Bogani, 2015).

Other studies did not find power morcellation to be a risk to women, despite Food and Drug Administration warnings:

1. A review of Norwegian women with uterine leiomyosarcoma concluded that power morcellators may be used in selected cases of symptomatic, presumed benign uterine leiomyomas (Skorstad, 2016).
2. A study of 3,021 patients found that “incidental morcellation” did not appear to create a risk for sarcoma dissemination (Zhang, 2016).
3. Another study found the risk of unintended morcellation of uterine leiomyosarcoma after preoperative selection of women with fibroids to be “very low” (Lieng, 2015).
4. A study of 358 women undergoing laparoscopic hysterectomy found no unexpected malignancies or elevated complication rate after undergoing supracervical surgery, i.e., with morcellation (Smits, 2016).
5. A systematic review of eight studies (n = 293) addressed submucous myomas removed by morcellator. Significantly reduced operative time compared to traditional resectoscopy was observed in some studies, and no differences in others. Authors concluded use of morcellators appears feasible surgical option in terms of operative time and complications (Vitale, 2017).
6. A meta-analysis of four trials (n = 392) of removal of endometrial lesions showed hysteroscopic morcellation had significantly better outcomes in successful removal of all lesions (P < .001) and total operative time (P < .001), with no significant difference in complication rate (Li, 2017).
7. A systematic review and meta-analysis of seven studies (n = 650), four of which were controlled, found that compared to resection, hysteroscopic morcellation with electrosurgical resection to treat uterine cavitary lesions was superior in total procedure time, smaller fluid deficit, and odds of complete lesion removal. Odds of surgical complications were similar (Shazly, 2016).
8. A panel of Canadian experts supported the use of laparoscopic power morcellation for uterine surgery, provided patients are advised of potential risks (Singh, 2015).
Some evidence does show adverse effects of using a morcellator. A 2017 study of 125 women documented a death rate three times greater ($P < .02$) risk of death within two years for women undergoing morcellation for benign uterine myoma, and later diagnosed with stage one uterine sarcoma. In addition, the risk of smooth muscle tumors of uncertain malignant potential for the morcellation group was higher, and close to statistically significant at $p < .09$ (Raspagliesi, 2017).

A review of 3-D ultrasound concluded the test was a good predictor to identify which women undergoing hysterectomy were candidates for morcellation. The key factor was the volume of the uterus; if 3-D ultrasound found a volume under 120 ml, the patient was very unlikely to benefit from morcellation (Gerges, 2016).

After a two-year follow-up, researchers at Massachusetts General Hospital found that contained power morcellation of unsuspected high-grade leiomyosarcomas might minimize the risk for women with laparoscopic hysterectomy (Boruta, 2016).

The recall of morcellators has changed practices among gynecological surgeons. An early 2015 survey completed by 518 Society of Laparoendoscopic Surgeons showed 61 percent were not using intracorporeal power morcellators, mostly because these devices had been returned to the company or were otherwise not available. Senior attending physicians used morcellators more frequently than junior attending physicians or fellows; the difference is significant at $P < .007$. Finally, 76 percent perform laparotomy in less than one-fourth of their cases, indicating that laparoscopy is still frequently being used (Nezhat, 2017).

A survey of eight gynecologists at a Washington medical center compared hysterectomy practices for the years prior to and after July 2014, when the morcellator was removed from the center ($n=100, 133$). In Year 2, laparoscopic supracervical hysterectomies were not performed. No uterine sarcomas were observed in Year 2 patients, and rates of blood loss, surgical site infections, operative time, and length of stay were unchanged, leading researchers to conclude that morcellator removal did not alter outcomes (Wesol, 2017).

Physician reactions to the Food and Drug Administration warning may be mixed. A survey of 426 gynecologists and oncology gynecologists in Italy found that 58.7 percent would only change their approach to avoid litigation, although 93.9 percent were aware of the warning (Mandato, 2016). Another study looked at utilization changes and outcomes of hysterectomy patients ($n = 15,546$) in Michigan in the 15 months before and eight months after the initial April 2014 warning. Utilization of laparoscopic hysterectomy fell 4.1 percent, major surgical complications rose 27.3 percent, and 30-day hospital readmissions rose 23.5 percent (Harris, 2016).

More research is needed to better understand risks and decide when morcellation.

**Policy updates:**
Three new practice guidelines/other and three new peer-reviewed references were added to, and four peer-reviewed references removed from, this policy in June, 2018.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harris (2016)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td></td>
<td>• Michigan hysterectomy patients (n = 18,299) with no indication of cancer.</td>
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<td></td>
<td>• Comparison of utilization 15 months before and eight months after FDA communication.</td>
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<tr>
<td></td>
<td>• Utilization of laparoscopic hysterectomy fell 4.1 percent (%).</td>
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<td></td>
<td>• Major surgical complications rose 27.3% (2.2 to 2.8 per 100).</td>
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<td></td>
<td>• Thirty-day hospital readmissions rose 23.5% (3.4 to 4.2 per 100).</td>
</tr>
<tr>
<td>Raine-Bennett (2016)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td></td>
<td>• Hysterectomies for leiomyoma from 2006 to 2013 through the Kaiser Permanente system (n = 34,728).</td>
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<tr>
<td></td>
<td>• Of the patients, 125 were diagnosed with uterine sarcomas.</td>
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<td></td>
<td>• Higher death rates one year after surgery for those with morcellation versus no morcellation.</td>
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<tr>
<td></td>
<td>• No significant differences between groups for death rates three years post-operative.</td>
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<tr>
<td>Zhang (2016)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td></td>
<td>• From 2009 to 2013, 3,021 patients were studied, with 78.5% having transvaginal scalpel morcellation.</td>
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<tr>
<td></td>
<td>• Eighteen had an unexpected uterine sarcoma.</td>
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<td></td>
<td>• All survived without recurrence, both with and without morcellation, for 25 to 32 months.</td>
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<tr>
<td></td>
<td>• Incidental morcellation “seems to cause no additional increase in sarcoma dissemination.”</td>
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<tr>
<td>Lieng (2015)</td>
<td><strong>Key points:</strong></td>
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<td></td>
<td>• Of the 4,791 women studied, 1,957 procedures were performed, 1,846 with morcellator.</td>
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<tr>
<td></td>
<td>• Twenty-six of these cases were diagnosed with uterine leiomyosarcoma.</td>
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<td></td>
<td>• Risk of unintended morcellation “appears to be very low.”</td>
</tr>
</tbody>
</table>

References

Professional society guidelines/other:


**Peer-reviewed references:**


**Centers for Medicare & Medicaid National Coverage Determinations:**

No National Coverage Determinations identified as of the writing of this policy.

**Local Coverage Determinations:**

No Local Coverage Determinations identified as of the writing of this policy.

**Commonly submitted codes:**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>58541</td>
<td>Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g for less</td>
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<tr>
<td>58542</td>
<td>Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g for less; with removal of tube(s) and/or ovary(s)</td>
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<tr>
<td>58543</td>
<td>Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 grams</td>
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<td>58544</td>
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<td>58545</td>
<td>Laparoscopy, surgical, myomectomy, excision; 1 to 4 intramural myomas</td>
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<td>58546</td>
<td>Laparoscopy, surgical, myomectomy, excision; 5 or more intramural myomas</td>
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<th>ICD-10 Code</th>
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<td>C55</td>
<td>Malignant neoplasm of uterus, part unspecified</td>
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<tr>
<td>D25.0</td>
<td>Submucous leiomyoma of uterus</td>
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<tr>
<td>D25.1</td>
<td>Intramural leiomyoma of uterus</td>
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<td>D25.2</td>
<td>Subserosal leiomyoma of uterus</td>
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<tr>
<td>D25.9</td>
<td>Leiomyoma of uterus, unspecified</td>
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<table>
<thead>
<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>C1782</td>
<td>Morcellator</td>
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