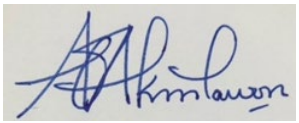
Prior Authorization Review Panel

MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: Keystone First Community HealthChoices	**Submission Date**: September 28, 2021
Policy Number: CCP.1130	**Effective Date:** 1/2015 **Revision Date:** September 7, 2021
Policy Name: Leiomyosarcoma and laparoscopic power morcellation	
Type of Submission – Check all that apply: ☐ **New Policy** ☑ **Revised Policy*** ☐ **Annual Review – No Revisions** ☐ **Statewide PDL**	
***All revisions to the policy must be highlighted using track changes throughout the document.** **Please provide any clarifying information for the policy below:** Please see revisions below using tracked changes.	
Name of Authorized Individual (Please type or print): Akintayo Akinlawon, MD	**Signature of Authorized Individual:** 

Keystone First
Community HealthChoices

Leiomyosarcoma and laparoscopic power morcellation

Clinical Policy ID: CCP.1130

Recent review date: 9/2021

Next review date: 1/2023

Policy contains: Hysterectomy, leiomyoma, leiomyosarcoma, myomectomy, power morcellation, uterine fibroids, uterine sarcoma.

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' 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 Keystone First Community HealthChoices 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. Keystone First Community HealthChoices' 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. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

Laparoscopic power morcellation is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

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 3% to 5% 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 66%, 34%, and 13% for localized, regional, and distant, respectively, based on 2010 – 2016 data (American Cancer Society, 2021).

Laparoscopic power morcellation, introduced in 1993, is a 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 (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 (Food and Drug Administration, 2014a).

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 (Stewart, 2021).

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 (Llamas, 2015). 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 Administration also advised physicians to discuss the risk with patients and urged manufacturers to include warnings on product labels (Food and Drug Administration, 2014b).

The Administration issued a release, acknowledging numerous correspondence from health professionals who insisted 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. Using a data base of 23 studies, ranging from 232 to 137,000 morcellation procedures for presumed fibroids, the review determined that unexpected uterine sarcomas and leiomyosarcomas occurred in 0.5% of cases, about two-thirds of these being uterine sarcomas (Food and Drug Administration, 2017).

The Administration also issued guidance on ways to make morcellators safer, namely, that they are only to be used for gynecological surgery with tissue containment systems and only in appropriately selected patients (Food and Drug Administration, 2020a; 2020b).

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

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).

Findings

An American College of Obstetricians and Gynecologists committee acknowledges that morcellation of a malignancy is contraindicated but such malignancies are very difficult to identify. The committee also stated that doctor and patient should engage in shared decision making, including informed consent explaining the risks and benefits of each approach to surgery for presumed leiomyomas, and alternatives to morcellation (American College of Obstetricians and Gynecologists, 2019).

The Canadian Task Force on Preventive Health Care concluded that women should be counselled that use of a morcellator for unexpected uterine (sarcoma, endometrial), cervical, and/or tubo-ovarian cancer, is associated with elevated risk of tumor dissemination. The group also adds that tissue morcellation should be performed only after complete investigation, appropriate patient selection, and informed consent and by surgeons with appropriate training in the safe practices of tissue morcellation (Muri, 2019).

Research on the use of power morcellation in women with uterine fibroids continued even after the Food and Drug Administration issued its initial 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). A questionnaire of gynecology surgeons in the United Kingdom revealed that 89% of the 187 respondents still used power morcellators for laparoscopic myomectomy and laparoscopic total hysterectomy (Sankaran, 2019).

Another 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%) and intra-abdominal (39% versus 9%) recurrence rate, and a higher (48% versus 29%) death rate (Bogani, 2015).

A review of 5,826 laparoscopic surgical procedures for presumed uterine fibroids at an institution in Italy from 2003 to 2019 revealed a total of 48 patients diagnosed with uterine sarcoma. Of these, 39 (81.3%) were recognized as suspicious uterine sarcomas during the preoperative assessment, avoiding morcellation. The occurrence of unexpected uterine sarcomas was 0.1% (6/5826), leading authors to tout the benefits of an accurate preoperative evaluation to reduce unexpected sarcomas (Surace, 2021).

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

- 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).
- A study of 3,021 patients found that "incidental morcellation" did not appear to create a risk for sarcoma

dissemination (Zhang, 2016).

- Another study found the risk of unintended morcellation of uterine leiomyosarcoma after preoperative selection of women with fibroids to be “very low” (Lieng, 2015).
- 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).
- 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).
- 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).
- 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).
- A panel of Canadian experts supported the use of laparoscopic power morcellation for uterine surgery, provided patients are advised of potential risks (Singh, 2015).
- A systematic review of 17 studies observed no differences in patient outcomes between power morcellation of occult leiomyosarcoma and en bloc uterine and tumor removal, and that the issue of unique dangers required more research before policies are accepted (Pritts, 2015).

Other evidence does show adverse effects of using a morcellator. A 2017 study of 125 women documented a death rate three times greater ($P < .02$) 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 study of 4,478 Chinese women who underwent laparoscopic hysterectomy/myomectomy with electric power morcellation for presumed leiomyomas showed 24 (0.54%) developed unexpected cancers, judged by the authors to be a “considerable risk” (Chen, 2018).

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).

A Chinese study of 26,643 patients with hysterectomy or myomectomy through laparoscopy or laparotomy for preoperatively presumed uterine leiomyomas from 2009 - 2016 found 11 patients had morcellation of uterine sarcoma, and 88 with uterine sarcomas (prevalence = 0.33%). The 48 endometrial stromal sarcoma patients with advanced stage had worse overall survival ($P < .01$) (Cao, 2019).

A study of 3,759 women undergoing hysterectomy for benign reasons in Olmsted County MN from 1999 to 2013 identified 16 sarcomas, of which 1 of 752 surgeries (0.13%) were suspected pre-operatively. The figure was 1 of 256 (0.39%) for women with uterine fibroids (1 of 256) (Multinu, 2019).

A review included women 18-55 who underwent laparoscopic or abdominal myomectomy after the release of the Food and Drug Administration warning. African Americans showed a significantly greater change in the odds of abdominal myomectomy over laparoscopic myomectomy compared to whites ($P = .03$) (Matsushita, 2020).

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% were not using intracorporeal powermorcellators, 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% of gynecological surgeons 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% would only change their approach to avoid litigation, although 93.9% 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%, major surgical complications rose 27.3%, and 30-day hospital readmissions rose 23.5% (Harris, 2016).

Researchers are now studying safety of morcellation using a tissue containment system. A Cochrane review of two studies (n = 176) compared premenopausal women with fibroids undergoing laparoscopic myomectomy. Some procedures used morcellation, during which each enucleated myoma was placed into a specimen retrieval bag and manually morcellated with scalpel or scissors; in others, intracorporeal uncontained power morcellation was used. No intraoperative complications or post-operative diagnoses of leiomyosarcoma were reported, and surgical time was slightly longer for in-bag morcellation. Authors could not make a judgement on effectiveness of the retrieval bag, noting that larger studies are needed (Zullo, 2020).

A study of 88 women with leiomyoma or endometrial cancer who underwent surgery from 2003 to 2014 with manual uterine morcellation within a plastic specimen bag showed no cases of occult leiomyosarcoma and all specimens were successfully manually morcellated within a bag (Dotson, 2018).

A review of 85 women who underwent laparoscopic hysterectomy or myomectomy who required morcellation of uterine tissue for specimen extraction were randomized to groups with uncontained (n = 49) and in-bag (n = 36) power morcellation of uterine tissue. Mean operating room time was longer in the in-bag morcellation group (119.0 versus 93.1 minutes, $P = .02$). No difference existed between groups in estimated blood loss, specimen weight, hospital length of stay, and perioperative complication rate, and no cases of malignancy or isolation bag disruption were observed (Vargas, 2015).

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On June 14, 2021, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the

Centers for Medicare & Medicaid Services. Search terms were “leiomyoma,” “leiomyosarcoma,” “morcellation,” “myomectomy,” “uterine fibroids,” and “uterine sarcoma.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

8/2014: initial review date and clinical policy effective date: 1/2015

8/2015: Policy references updated.

8/2016: Policy references updated.

8/2017: Policy references updated.

8/2018: Policy references updated.

9/2019: Policy references updated. Policy ID changed to CCP.1130.

9/2020: Policy references updated.

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