Clinical Policy Title: Leiomyosarcoma and Laparoscopic Power Morcellation

Clinical Policy Number: 12.03.01

Effective Date: Jan. 1, 2015
Initial Review Date: Aug. 20, 2014
Most Recent Review Date: Sept. 17, 2014
Next Review Date: August, 2015

Policy contains:
- Power Morcellation
- Leiomyosarcoma
- Hysterectomy
- Uterine fibroids

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ 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 AmeriHealth Caritas 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. AmeriHealth Caritas’ 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. AmeriHealth Caritas’ clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

Coverage policy
AmeriHealth Caritas considers the use of laparoscopic power morcellation to be investigational 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 3-5% of all uterine cancer diagnosis in the US. It arises from the myometrium or connective tissue of the uterus. Uterine sarcomas are highly aggressive, with 5-year overall survival rates ranging between 17 and 55%.

Laparoscopic power morcellation is a minimally invasive technique used to treat uterine fibroids, such as removing the uterus or removing uterine fibroids. Morcellation devices generally cut tissue into smaller fragments to facilitate removal of tissue through small incisions. Recent clinical information suggests laparoscopic power morcellation poses a risk of spreading unsuspected cancerous tissue such as uterine sarcomas to travel beyond the uterus. On April 17, 2014, the U.S. Food and Drug Administration (FDA) withdraw approval of laparoscopic power morcellators because of this risk of spreading cancer.

Although many women develop uterine fibroids in their lifetime, most cause no symptoms. Some cases result in heavy or prolonged menstrual bleeding, pelvic pressure or pain, or frequent urination. 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. 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 FDA.

On July 30, 2014, a morcellation device manufacturer instituted a recall on all its morcellation devices, citing uncertainty in the risk-benefit assessment associated with the use of power morcellators.

Methods

Searches:
AmeriHealth Caritas 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.

Searches were conducted on August 11, 2014 using the terms “Leiomyosarcoma” and “laparoscopic power morcellation”. Included were:
- 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

Summary of Clinical Evidence

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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</thead>
</table>
| **Felix – Etiology of Uterine Sarcomas** | **Key Point**  
• Significant risk factors for uterine sarcoma included obesity and history of diabetes.  
• Older age at menarche was inversely associated with uterine sarcoma risk.  
• BMI was significantly, but less strongly related to uterine sarcomas compared with EECs or MMMTs. |
| **Shibley – Safety Techniques Regarding Morcellation** | **Key Point**  
• Inflation of a morcellation bag creates an artificial pneumoperitoneum possibly creating a safe environment for the morcellation procedures. |

Glossary

**Uterine fibroids**- Noncancerous growths that develop from the muscular tissue of the uterus.

References

Professional society guidelines/others:


Peer-reviewed references:


Clinical Trials:

<table>
<thead>
<tr>
<th>Name of Trial:</th>
<th>ClinicalTrials.gov Identifier:</th>
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<tbody>
<tr>
<td>Intracorporeal Versus Extracorporeal Morcellation: Clinical Efficacy and Safety Outcomes (IEME)</td>
<td>NCT02086435</td>
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</table>
Centers for Medicare and Medicaid Services (CMS) National Coverage Determination

There is no national coverage determination related to this policy.

Local Coverage Determinations

There are no local coverage determinations related to 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 in accordance with those manuals.

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<tr>
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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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<td>58543</td>
<td>Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 grams</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>
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<td>179</td>
<td>Malignant neoplasm, sarcoma, uterus</td>
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<tr>
<td>171.9</td>
<td>Leiomyosarcoma, uterus</td>
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<td>218.9</td>
<td>Uterine Fibroid</td>
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