



Kansas City

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Surgical Interruption of Pelvic Nerve Pathways for Primary and Secondary Dysmenorrhea

Policy Number: 4.01.17
Origination: 11/2007

Last Review: 11/2013
Next Review: 11/2014

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for surgical interruption of pelvic nerve pathways for primary and secondary dysmenorrhea. This is considered investigational.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

Laparoscopic uterine nerve ablation (LUNA) and laparoscopic presacral neurectomy (LPSN) are considered **investigational** as techniques to treat primary or secondary dysmenorrhea.

Considerations

Conservative surgical therapy includes ablation or excision of endometrial deposits or lysis of pelvic adhesions, typically performed during laparoscopy. Presacral neurectomy may be performed at the time of this laparoscopy.

Description of Procedure or Service

Two laparoscopic surgical approaches are proposed as adjuncts to conservative surgical therapy for the treatment of primary and secondary dysmenorrhea. These approaches are laparoscopic uterine nerve ablation (LUNA) and presacral neurectomy (PSN).

Dysmenorrhea is defined as the occurrence of painful menstrual cramps. Primary dysmenorrhea occurs in the absence of an identifiable cause, while secondary dysmenorrhea is related to an identifiable pathologic condition, such as endometriosis, adenomyosis, or pelvic adhesions. The etiology of primary dysmenorrhea is incompletely understood but is thought to be related to the overproduction of uterine prostaglandins. Therefore, first-line pharmacologic therapy typically includes nonsteroidal anti-inflammatory drugs (NSAIDs), which reduce prostaglandin production. Oral contraceptives are another approach. Patients with secondary dysmenorrhea may be offered both NSAIDs and oral contraceptives, as well as a variety of other hormonal therapies. Patients with endometriosis frequently undergo surgery to ablate, excise, or enucleate endometrial deposits or lyse pelvic adhesion. Collectively, these surgical procedures may be referred to as “conservative surgical therapy.”

Uterine nerve ablation (UNA) and presacral neurectomy (PSN) are two laparoscopic surgical approaches that have been investigated as techniques to interrupt the majority of the cervical sensory nerve fibers in patients with dysmenorrhea. UNA involves the transection of the uterosacral ligaments at their insertion into the cervix, while PSN involves the removal of the presacral nerves lying within the interiliac triangle. PSN interrupts a greater number of nerve pathways compared to laparoscopic uterine nerve ablation (LUNA), and is technically more demanding. Either LUNA or PSN can be performed as adjuncts to conservative surgical therapy in patients with secondary dysmenorrhea.

Rationale

This policy was originally created in 2004 and was updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period January 2012 through February 20, 2013. Following is a summary of key literature.

Systematic Reviews

A 2005 Cochrane review of surgical interruption of pelvic nerve pathways for primary and secondary dysmenorrhea concluded that, “there is insufficient evidence to recommend the use of nerve interruption in the management of dysmenorrhea, regardless of cause.” (1) The same authors published a systematic review in 2007 that included 1 additional study in the meta-analysis, for a total of 9 randomized trials including 773 women. (2) Eligible studies were prospective, randomized, controlled trials (RCTs) comparing surgical interruption of pelvic nerve pathways to no treatment or another treatment in women with primary or secondary dysmenorrhea. Studies of secondary dysmenorrhea associated with the use of intrauterine contraceptive devices were excluded. The primary outcome in all the reviewed trials was pain relief, which was measured and reported in a variety of ways. The 2007 systematic review concluded that evidence remained insufficient to determine whether surgical interruption of pelvic nerve pathways is effective. For LUNA, questions remained concerning the durability of the procedure, the risk of anatomical distortion, and the effect on subsequent pregnancies. The authors also concluded that due to the difficulty of PSN and its related risks, this procedure should be performed by a highly skilled surgeon trained specifically in this operation, within the setting of controlled trials and with full disclosure about the potential hazards.

Randomized controlled trials

Conventional treatment plus LUNA versus conventional treatment alone

The 2007 systematic review discussed above (2) identified 2 trials that compared laparoscopic uterine nerve ablation (LUNA) with diagnostic laparoscopy alone. (3, 4) The smaller trial (n=21 (3) measured pain on a 5-point pain scale, and the other study (n=56 [4]) used a visual analog scale (VAS). A pooled analysis of these trials (2) found that, at 6 months or less follow-up, there was no significant difference between groups in pain relief (odds ratio [OR]: 1.43; 95%, confidence interval [CI]: 0.56–3.69). However, at 12 months, there was greater pain relief with LUNA (OR: 6.12; 95%, CI: 1.78-21.03). These studies included a relatively small number of women, and estimates of effectiveness were imprecise, as evidenced by the wide CIs.

Three trials compared LUNA plus conservative surgery to conservative surgery alone. (4-6) A fourth trial compared LUNA plus laparoscopic bipolar coagulation of uterine vessels with laparoscopic bipolar coagulation of uterine vessels only for women with uterine myomas. (7) No significant difference in pain relief was found in pooled analyses of 3 trials after 6 months or less follow-up (n=190; OR: 1.03; 95%, CI: 0.52–2.02) or of 2 trials with up to 12 months of follow-up (n=217; OR: 0.77; 95%, CI: 0.43–1.39). There were also no significant differences between groups in quality of life, anxiety, or depression.

Additional trials since the 2007 systematic review have compared LUNA with diagnostic laparoscopy to diagnostic laparoscopy alone. A 2009 study from the U.K. included women who had chronic pelvic pain lasting longer than 6 months and who had not been diagnosed with moderate-to-severe endometriosis or major pelvic inflammatory disease. (8) Forty-five percent of the sample had some type of visible pathology; 17% minimal endometriosis and 20% had adhesions. LUNA after diagnostic laparoscopy (n=243) was compared to diagnostic laparoscopy alone (n=244) for women with primary dysmenorrhea. The primary outcome was patient-rated pain using a 10-cm visual analog scale (VAS) score. Patients were asked about 3 types of pain (nonyclical pain, dysmenorrhea, and dyspareunia). At 12-month follow-up, pain data were missing for 51 women (21%) in the LUNA group and 48 (20%) women in the control group; an additional 5 women in the LUNA group and 4 women in the control group withdrew consent during the first year of follow-up. At 12 months, there was no significant difference between groups in any of the types of pain or in the worst pain level of any type. There was also no significant difference between groups in any of the pain outcomes when the difference in pain was measured over all timepoints (outcomes were assessed at 3 and 6 months and 1, 2, 3, and 5

years). The median time in the study was 69 months; 72% of women had at least 5 years of follow-up. Note that actual VAS scores for each group were not reported but were represented on figures. Advantages of this study include longer-term follow-up, blinding of subjective outcomes, and randomization after inspection of the pelvis to ensure eligibility.

A 2011 RCT by El-Din Shawki, conducted in Egypt, included women with pelvic pain and excluded those with moderate to severe endometriosis or previous surgery for endometriosis or for pelvic inflammatory disease. (9) A total of 190 women were randomized, 95 to each group. A total of 171/190 (90%) completed the 12-month follow-up. Clinical success was defined as the percentage of women who reported no, minimal or tolerable pain during the follow-up period without hysterectomy or repeated LUNA. At 12 months, the clinical success rate was 63/86 (73%) in the LUNA group and 63/85 (74%) in the control group; the difference between groups was not statistically significant. Moreover, there was not a statistically significant difference between groups in dysmenorrhea and most other efficacy variables. The only statistically significant difference, favoring the LUNA group, was in the rate of dyspareunia

Conclusions: Several RCTs have compared conventional treatment to conventional treatment plus LUNA. The results of these trials generally indicate that outcomes of conventional treatment are similar to outcomes of conventional treatment plus LUNA. This evidence suggests that LUNA does not offer incremental benefit above that of conventional treatment for the treatment of dysmenorrhea.

Conventional treatment plus presacral neurectomy versus conventional treatment alone
No RCTs were identified that evaluated presacral neurectomy (PSN) for treatment of primary dysmenorrhea.

For secondary dysmenorrhea, 3 trials compared presacral neurectomy plus conservative surgery to conservative surgical therapy alone in patients with endometriosis. (5, 6, 10, 11) A pooled analysis of 2 trials with 197 women found a significant difference between treatment groups, favoring the PSN group (OR: 3.14; 95%, CI: 1.59–6.21). Two of the trials were published in the early 1990s. The largest and most recent trial, published by Zullo and colleagues in 2003, randomized 141 women and included 126 women in the analysis. (11) The primary outcome was the cure rate, defined as the percentage of patients who reported an absence of dysmenorrhea or dysmenorrhea that did not require medical treatment. At 6 and 12 months, the cure rate for the treatment and control groups was 87.3% versus 60.3% and 85.7% versus 57.1%, respectively. While there was no difference in short-term complications between the 2 groups, at 12 months, 14.3% of the presacral neurectomy group reported constipation, compared to none in the control group. While the results of this trial are positive, several factors limit its interpretation. All of the surgeries were performed by one physician, which raises questions about whether the results can be generalized. In addition, although the trial reported using an intent-to-treat (ITT) analysis, 15 of the 141 randomized subjects were not included in the analysis.

An updated report on the participants in the Zullo et al. trial found that, at 24 months, outcomes continued to be better in the PSN group and the overall complication rate in the PSN group continued to be higher. (12) The cure rate (absence of dysmenorrhea) was higher for the PSN group (34.4%) compared to the control laparoscopy group (18%). The percentage of women with dysmenorrhea not requiring medical attention was 82% and 65.6% in the PSN and control group, respectively. However, 11 (18.3%) women in the PSN group had long-term complications consisting of bowel and urinary dysfunction, compared to none in the control laparoscopy group. This high complication rate raises questions regarding the risk-benefit ratio of adding PSN to a conservative laparoscopic therapy.

Conclusions: There is limited clinical trial evidence on the benefit of presacral neurectomy for secondary dysmenorrhea. Some of these trials report that symptoms are reduced to a greater extent with presacral neurectomy compared to conventional therapy alone. However, adverse events, primarily constipation, are also increased following presacral neurectomy. Further RCTs are needed to better define the risk/benefit ratio and the patient population that might benefit from this treatment.

LUNA versus presacral neurectomy

The only randomized study on this topic was a 1996 study by Chen and colleagues that randomized 68 patients to undergo either LUNA or PSN. (13) The procedure was considered a success if there was at least a 50% reduction in pain. While there was no significant difference in the 2 procedures at 6 months, PSN was associated with improved pain relief compared to LUNA at greater than 6 months. However, the incidence of adverse effects was greater with PSN; specifically, 94% of patients randomized to PSN reported constipation.

Summary

The evidence is insufficient to form conclusions on whether laparoscopic uterine nerve ablation (LUNA) improves health outcomes in patients with primary or secondary dysmenorrhea. Studies comparing LUNA to diagnostic laparoscopy alone have not found a consistent benefit for the addition of LUNA to diagnostic laparoscopy. In addition, sample sizes were small in many studies, and there are few studies with follow-up of 12 months or longer.

The evidence on presacral neurectomy for treating primary dysmenorrhea is also insufficient to form conclusions; no randomized trials were identified in patients with primary dysmenorrhea. For secondary dysmenorrhea, only one recent well-conducted trial on presacral neurectomy was identified; this trial found improvement in pain outcomes but also higher complication rates. The net health benefit remains unclear and needs to be further assessed in additional trials.

Due to the limitations of the available literature and lack of support in specialty society guidelines, laparoscopic uterine nerve ablation and presacral neurectomy are considered investigational for the treatment of primary and secondary dysmenorrhea.

Practice Guidelines and Position Statements

In March 2004 (reaffirmed in 2008), American College of Obstetricians and Gynecologists (ACOG) issued a practice bulletin on chronic pelvic pain. (14) The practice bulletin includes the following statements: "Presacral neurectomy may be considered for treatment of centrally located dysmenorrhea but has limited efficacy for chronic pelvic pain or pain that is not central in its location. Uterine nerve ablation or transaction of the uterosacral ligament also can be considered for centrally located dysmenorrhea, but it appears to be less effective than presacral neurectomy. Combining uterine nerve ablation or presacral neurectomy with surgical treatment of endometriosis does not further improve overall pain relief."

In October 2007, National Institute for Health and Clinical Excellence (NICE) issued interventional procedure guidance number 234 on LUNA for chronic pelvic pain. (15) The guidance states "The evidence on laparoscopic uterine nerve ablation (LUNA) for chronic pelvic pain suggests that it is not efficacious and therefore should not be used."

Medicare National Coverage

No national coverage determination.

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Billing Coding/Physician Documentation Information

58579 Unlisted hysteroscopy procedure, uterus

There is no specific CPT code for laparoscopic uterine nerve ablation or presacral neurectomy. CPT code 58578 (unlisted laparoscopy procedure, uterus) may be used. For secondary dysmenorrhea, presacral neurectomy may be performed in conjunction with either of the following procedures:

- 58660: Laparoscopy, surgical; with lysis of adhesions
- 58662: Laparoscopy, surgical; with fulguration or excision of lesions of the ovary, pelvic viscera, or peritoneal surface by any method

Additional Policy Key Words

N/A

Policy Implementation/Update Information

11/1/07	New policy, considered investigational.
11/1/08	No policy statement changes.
11/1/09	No policy statement changes.
11/1/10	No policy statement changes.
11/1/11	No policy statement changes.
11/1/12	No policy statement changes.
11/1/13	No policy statement changes.

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