UnitedHealthcare®

MEDICAL POLICY

PRESACRAL NEURECTOMY AND UTERINE NERVE ABLATION FOR PELVIC PAIN

Policy Number: 2014T0059K
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Related Policies:
Abnormal Uterine Bleeding and Uterine Fibroids

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Essential Health Benefits for Individual and Small Group:
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage.

COVERAGE RATIONALE

Presacral neurectomy is proven and medically necessary for treating women with primarily midline pelvic pain unresponsive to medical therapy, which includes the following:

- A 3-month trial of oral contraceptives; **or**
- If oral contraceptives are contraindicated, menstrual suppression with progesterone or gonadotropin-releasing hormone (GnRH) agonist therapy.

Presacral neurectomy is unproven and not medically necessary for treating lateral pelvic pain or symptoms other than midline pelvic pain.

There is a lack of evidence that presacral neurectomy provides a clinical benefit in these patient populations.

Uterine nerve ablation (UNA) and laparoscopic uterine nerve ablation (LUNA) are unproven and not medically necessary for treating chronic pelvic pain associated with dysmenorrhea or endometriosis.

There is insufficient evidence in the published clinical literature establishing the effectiveness of UNA and LUNA for the treatment of dysmenorrhea. The durability of pain relief from UNA and LUNA will determine the potential beneficial effect on health outcomes. This will require well-designed clinical studies with long-term results.

APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and/or Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

CPT® Code	Description
58578	Unlisted laparoscopy procedure, uterus
58999	Unlisted procedure, female genital system (nonobstetrical)
64999	Unlisted procedure, nervous system

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DESCRIPTION OF SERVICES

Chronic pelvic pain (CPP) is defined as pain in the pelvic area that lasts for 6 months or longer (American College of Obstetricians and Gynecologists, 2011). CPP includes primary and secondary dysmenorrhea, chronic painful conditions of the pelvis that occur during menstruation. Primary dysmenorrhea refers to pain without a known cause. Secondary dysmenorrhea refers to pain associated with a physical cause such as endometriosis or pelvic adhesions. Treatments for primary dysmenorrhea are aimed at providing relief of symptoms and include over-the-counter (OTC) and prescription pain relief medications and oral contraceptives.

Presacral neurectomy and uterine nerve ablation are two surgical procedures that are used for individuals who do not respond to medication and who continue to suffer from severe primary dysmenorrhea and/or chronic pelvic pain. Presacral neurectomy interrupts the sympathetic nerves of the uterus near the superior hypogastric plexus. Laparoscopic uterine nerve ablation (LUNA) destroys uterine nerve fibers as they leave the uterus via the uterosacral ligaments (ECRI, 2011).

CLINICAL EVIDENCE

An Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness report on therapies for noncyclic chronic pelvic pain (CPP) concluded that no surgical technique was superior, and the evidence to conclude that surgical intervention is either effective or ineffective for the treatment of CPP is insufficient. Among studies addressing treatment effects, little evidence demonstrates the effectiveness of surgical approaches. Despite numerous surgical techniques used extensively in treating CPP, few studies included more than 50 participants, and few were considered high quality. All of the studies with comparison data failed to demonstrate that surgery in general or any specific surgical technique was more efficacious than either nonsurgical intervention or the comparator technique in improving pain status in patients (Andrews et al., 2012).

In a systematic review of seven Cochrane review articles and 35 randomized trials evaluating laparoscopic management of endometriosis, Yeung et al. (2009) concluded that laparoscopic presacral neurectomy, but not laparoscopic uterosacral nerve ablation, is a useful adjunct to conservative surgery for endometriosis in patients with a midline component of pain.

Latthe et al. (2007) conducted a systematic review of nine randomized controlled trials to assess the effectiveness of surgical interruption of the pelvic nerve pathways in primary and secondary dysmenorrhea. At 12 month follow-up, the authors found that for the treatment of primary dysmenorrhea, laparoscopic uterosacral nerve ablation (LUNA) was more effective when compared to no treatment. However, the comparison of LUNA with presacral neurectomy (PSN) for primary dysmenorrhea showed that PSN was more effective. In secondary dysmenorrhea, LUNA along with laparoscopic surgical treatment of endometriosis showed no improvement in pain relief while presacral neurectomy did. The authors concluded that while presacral neurectomy appears effective, evidence for nerve interruption procedures in the management of dysmenorrhea is limited; additional methodologically sound and sufficiently powered RCTs are needed.

In a systematic review, Cheong and William (2006) examined the current evidence on the etiology and management of chronic pelvic pain, focusing on the randomized controlled trials (RCTs) that are available to date. According to the reviewers, the short term results for presacral neurectomy (PSN) and laparoscopic utero-sacral nerve ablation (LUNA) seemed to be similar, although PSN has better results in the long term.

Proctor et al. (2005) conducted a Cochrane meta-analysis of eight randomized controlled trials comparing surgical techniques of interruption of the pelvic nerve pathways (using both open and laparoscopic procedures) for the treatment of primary and secondary dysmenorrhea. For the treatment of primary dysmenorrhea there was some evidence of the effectiveness of laparoscopic uterine nerve ablation (LUNA) when compared to a control or no treatment. The comparison between LUNA and laparoscopic presacral neurectomy (LPSN) for primary dysmenorrhea showed no significant difference in pain relief in the short term; however, long-term LPSN was shown to be significantly more effective than LUNA. For the treatment of secondary dysmenorrhea six identified RCTs addressed endometriosis and one included women with uterine myomas. The treatment of LUNA combined with surgical treatment of endometrial implants versus surgical treatment of endometriosis alone showed that the addition of LUNA did not aid pain relief. For PSN combined with endometriosis treatment versus endometriosis treatment alone there was an overall difference in pain relief although the data suggests this may be specific to laparoscopy and for midline abdominal pain only. Adverse events were significantly more common for presacral neurectomy; however, the majority were complications such as constipation, which may spontaneously improve. The authors concluded that there is insufficient evidence to recommend the use of nerve interruption in the management of dysmenorrhoea, regardless of cause. Future methodologically sound and sufficiently powered RCTs should be undertaken.

Presacral Neurectomy
Zullo et al. (2003) completed 2 randomized controlled trials to study the effectiveness of presacral neurectomy (PSN) in women with severe dysmenorrhea caused by endometriosis. The initial study involved 141 patients who were randomly assigned to either receive presacral neurectomy (71 patients) or not (70 patients). Patients were followed for 1 year. Patients receiving presacral neurectomy (PSN) had greater relief of symptoms than the non-PSN group. The second study, conducted at 24 months, reviewed response rate to PSN in 126 of the available 141 patients (Zullo, 2004). Six patients were excluded from follow-up due to additional surgery for recurrent endometriosis. At follow-up, 83.3% of the patients receiving PSN compared to 53.3% who did not showed complete relief of symptoms. Although PSN appeared to be more effective than surgery alone for the relief of endometriosis-associated pain, it resulted in a higher number of long-term complications, such as constipation (14%) and urinary urgency (5%); no long-term complications were observed in the patients who did not have PSN at the time of surgery.

Candiani et al. (1992) conducted a randomized, controlled trial of 71 patients to assess the efficacy of presacral neurectomy (PSN) combined with conservative surgery to treat pelvic pain associated with moderate to severe endometriosis and midline dysmenorrhea. Patients were randomly assigned to conservative surgery alone (36 patients) or conservative surgery and presacral neurectomy (35 patients). The results showed that while more PSN-treated patients were free of midline dysmenorrhea at 1 year compared with those who had laparotomy alone, the difference was not significant (66% versus 58%, respectively). There were no differences between the PSN and non-PSN groups with respect to improvement in or resolution of dyspareunia (84% and 67%, respectively) and intermenstrual pelvic pain (82% and 80%, respectively). The strengths of this study were its randomized, controlled trial design; defined pain measures; and power analysis to determine required sample size. Major weaknesses were lack of blinding and the fact that pain measures did not discriminate between midline and lateral pain.

A large retrospective analysis with 1 year of follow-up evaluated the efficacy and safety of laparoscopic presacral neurectomy (PSN) with ablation of endometriosis lesions or lysis of pelvic adhesions if needed in 655 patients with severe, disabling dysmenorrhea or CPP refractory to medical therapy (Chen, 1997). Of these, 390 patients had secondary dysmenorrhea related to endometriosis or adenomyosis, 99 had primary dysmenorrhea, and 166 had CPP. Laparoscopic PSN was efficacious for controlling pain in 73% and 75% of patients with moderate-to-severe and mild endometriosis, respectively, 77% of patients with primary dysmenorrhea, and 52% of patients with adenomyosis. The reduction in pain was significant for all groups (P=0.006). There were four major complications (0.6%) that required further surgery including injury of the right iliac artery (n = 1), and chylous ascites (n = 3). Three patients (0.5%) had laceration of the middle sacral vein during laparoscopy. A total of 485 (74%) patients had constipation that was controlled with medication.

Uterine Nerve Ablation
El-Din Shawki (2011) explored the efficacy, safety and patient satisfaction of laparoscopic uterosacral nerve ablation (LUNA) in the relief of chronic pelvic pain in women with no pathology or mild endometriosis. The study was a prospective, single-blind, randomized trial with 12 months follow-up. One hundred ninety women were randomized and divided into two equal groups. The control group had diagnostic laparoscopy with no pelvic denervation while the study group had diagnostic laparoscopy plus LUNA. At 3, 6, and 12 months follow-up, there was no statistically significant difference between groups for efficacy, overall success rate and patient satisfaction.

Using individual patient data (IPD), the International LUNA IPD Meta-analysis Collaborative Group evaluated the effects of laparoscopic uterosacral nerve ablation (LUNA) on chronic pelvic pain. Randomized trials comparing LUNA with no additional intervention were selected and authors contacted for IPD. Raw data were available from 862 women randomized into five trials. The authors found no significant difference between the treatment groups and concluded that LUNA does not result in improved chronic pelvic pain (Daniels, 2010).

Daniels et al. (2009) assessed the effectiveness of laparoscopic uterosacral nerve ablation (LUNA) in 487 women with chronic pelvic pain. Participants were randomized to receive bilateral LUNA (n=243) or laparoscopy without pelvic denervation (no LUNA) (n=244) and were blinded to the treatment allocation. Follow-up questionnaires were sent to the women at 3 and 6 months and at 1, 2, 3, and 5 years. The primary outcome was pain, which was assessed by a visual analogue scale. The secondary outcome was health-related quality of life, which was measured using a generic instrument (EuroQoL EQ-5D and EQ-VAS). After a median follow-up of 69 months, there were no significant differences reported on the pain scales between the two groups. No differences were observed between the LUNA group and the no LUNA group for quality of life. Among women with chronic pelvic pain, LUNA did not result in improvements in pain, dysmenorrhea, dyspareunia or quality of life compared with laparoscopy without pelvic denervation.

In a randomized controlled trial, 180 women underwent laparoscopic resection of the uterosacral ligaments to treat endometriosis and predominantly midline dysmenorrhea. Among the patients who were evaluable 1 year after operative laparoscopy, 23 of 78 (29%) women who had uterosacral ligament resection and 21 of 78 (27%) women who had conservative surgery only reported recurrent dysmenorrhea. The corresponding numbers of patients at 3 years were 21 of 59 (36%) women and 18 of 57 (32%) women, respectively. Time to recurrence was similar in the two groups. Pain was substantially reduced, and patients in both groups experienced similar and significant improvements in health-related quality of life, psychiatric profile and sexual satisfaction. Overall, 68 of 90 (75%) patients in the uterosacral ligament resection group and 67 of 90 (74%) patients in the conservative surgery group were satisfied at 1 year. Addition of uterosacral ligament resection to conservative laparoscopic surgery for endometriosis did not reduce the medium- or long-term frequency and severity of recurrence of dysmenorrhea (Vercellini, 2003).

Johnson et al. (2004) conducted a prospective, double-blind, randomized controlled trial with 123 women to determine the effectiveness of laparoscopic uterine nerve ablation (LUNA) for chronic pelvic pain (CPP). Women were randomized into two groups: those with endometriosis (n=67), and those with no laparoscopic evidence of endometriosis (n=56), to receive LUNA or no LUNA. Patients were followed for 12 months. The primary outcome measures were changes in non-menstrual pelvic pain, dysmenorrhea, deep dyspareunia and excessive straining with bowel movements as measured by visual analogue scores (VAS). There was a significant reduction in dysmenorrhea in women with CPP without endometriosis who underwent LUNA (p=0.039). There was no significant difference in non-menstrual pelvic pain, deep dyspareunia or excessive straining with bowel movements in women without endometriosis undergoing LUNA versus no LUNA. The addition of LUNA to laparoscopic surgical treatment of endometriosis was not associated with a significant difference in any pain outcomes. It was concluded that LUNA is effective for dysmenorrhea in the absence of endometriosis, although there is no evidence of effectiveness of LUNA for non-dysmenorrhea CPP or for any type of CPP related to endometriosis.

Palomba et al. (2006) compared laparoscopic uterine nerve ablation (LUNA) and vaginal uterosacral ligament resection (VUSR) in postmenopausal women with chronic pelvic pain (CPP). Eighty postmenopausal women with intractable and severe midline CPP were randomized to undergo LUNA or VUSR. Cure rate, severity of CPP, and deep dyspareunia were evaluated after 6 and 12 months from surgery. The cure rate was not significantly different between the two groups at 6 months and 12 months of follow-up. A significant decrease in severity of CPP and deep dyspareunia was observed in both groups with no difference between them. The investigators concluded that both LUNA and VUSR are equally effective surgical treatments in postmenopausal women with central CPP.

The National Institute for Health and Care Excellence (NICE) issued a guidance document concerning LUNA for chronic pelvic pain in 2007. According to NICE, the evidence on LUNA for chronic pelvic pain suggests that LUNA is not efficacious and therefore should not be used. This

conclusion was based on an evaluation of nine RCTs including 528 women treated with LUNA (NICE, 2007).

The clinical evidence was reviewed in July 2014 with no additional information identified that would change the conclusions.

Professional Societies

American Society for Reproductive Medicine (ASRM)

In a committee opinion on the treatment of pelvic pain associated with endometriosis, ASRM states the following:

- Presacral neurectomy has been proposed for treatment of midline pain associated with menses, because its effects on other components of pelvic pain have been inconsistent. However, it is important to recognize that presacral neurectomy is a technically challenging procedure associated with significant risk of bleeding from the adjacent venous plexus. Patients may also experience constipation and/or urinary retention postoperatively.
- LUNA does not appear to offer any added benefits beyond those that can be achieved with conservative surgery alone (ASRM, 2014).

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Presacral neurectomy (PSN) and uterine nerve ablation are surgical procedures, and therefore, are not subject to regulation by the FDA.

The laparoscopic equipment used in laparoscopic uterine nerve ablation (LUNA) is organized by the FDA into a number of product codes, all of which receive 510(k) clearance for marketing. These codes are not specific for LUNA, and the FDA database does not provide a single list of devices cleared specifically for LUNA.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for presacral neurectomy and uterine nerve ablation used in the treatment of chronic pelvic pain. Local Coverage Determinations (LCDs) do not exist at this time. (Accessed June 25, 2014)

REFERENCES

American College of Obstetricians and Gynecologists (ACOG). FAQ099. Chronic pelvic pain. August 2011. Available at: https://www.acog.org/~/media/For%20Patients/faq099.pdf?dmc=1&ts=20140715T1148278690. Accessed July 15, 2014.

American Society for Reproductive Medicine (ASRM). Treatment of pelvic pain associated with endometriosis: a committee opinion. Fertil Steril. 2014 Apr;101(4):927-35

Andrews J, Yunker A, Reynolds WS, et al. Noncyclic chronic pelvic pain therapies for women: comparative effectiveness. Rockville (MD): Agency for Healthcare Research and Quality (US); 2012 Jan. Available at: http://www.ncbi.nlm.nih.gov/books/NBK84586/. Accessed July 11, 2014.

Candiani GB, Fedele L, Vercellini P, et al. Presacral neurectomy for the treatment of pelvic pain associated with endometriosis: a controlled study. Am J Obstet Gynecol. 1992;167(1):100-103.

Chen FP, Soong YK. The efficacy and complications of laparoscopic presacral neurectomy in pelvic pain. Obstet Gynecol. 1997;90(6):974-977.

Cheong Y, William SR. Chronic pelvic pain: aetiology and therapy. Best Pract Res Clin Obstet Gynaecol. 2006;20(5):695-711.

Daniels J, Gray R, Hills RK, et al. LUNA Trial Collaboration. Laparoscopic uterosacral nerve ablation for alleviating chronic pelvic pain: a randomized controlled trial. JAMA. 2009 Sep 2;302(9):955-61.

Daniels JP, Middleton L, Xiong T, International LUNA IPD Meta-analysis Collaborative Group et al. Individual patient data meta-analysis of randomized evidence to assess the effectiveness of laparoscopic uterosacral nerve ablation in chronic pelvic pain. Hum Reprod Update. 2010 Nov-Dec;16(6):568-76.

ECRI Institute. Hotline Service. Laparoscopic uterosacral nerve ablation for dysmenorrhea. May 2011.

El-Din Shawki H. The efficacy of laparoscopic uterosacral nerve ablation (LUNA) in the treatment of unexplained chronic pelvic pain: a randomized controlled trial. Gynecol Surg. 2011 Feb;8(1):31-39.

Johnson NP, Farquhar CM, Crossley S, et al. A double-blind randomised controlled trial of laparoscopic uterine nerve ablation for women with chronic pelvic pain. BJOG. 2004 Sep;111(9):950-9.

Latthe PM, Proctor ML, Farquhar CM, et al. Surgical interruption of pelvic nerve pathways in dysmenorrhea: a systematic review of effectiveness. Acta Obstet Gynecol Scand. 2007;86(1):4-15.

National Institute for Health and Care Excellence (NICE). Laparoscopic uterine nerve ablation (LUNA) for chronic pelvic pain. IPG234. October 2007. Available at: http://www.nice.org.uk/nicemedia/pdf/IPG234Guidance.pdf. Accessed July 11, 2014.

Palomba S, Russo T, Falbo A, et al. Laparoscopic uterine nerve ablation versus vaginal uterosacral ligament resection in postmenopausal women with intractable midline chronic pelvic pain: a randomized study. Eur J Obstet Gynecol Reprod Biol. 2006;129(1):84-91.

Proctor M, Latthe P, Farquhar CM, et al. Surgical interruption of pelvic nerve pathways for primary and secondary dysmenorrhoea. Cochrane Database of Systematic Reviews 2005, Issue 4. Art. No.: CD001896.

Vercellini P, Aimi G, Busacca M, et al. Laparoscopic uterosacral ligament resection for dysmenorrhea associated with endometriosis: results of a randomized, controlled trial. Fertil Steril. 2003 Aug;80(2):310-9.

Yeung PP Jr, Shwayder J, Pasic RP. Laparoscopic management of endometriosis: comprehensive review of best evidence. J Minim Invasive Gynecol. 2009 May-Jun;16(3):269-81.

Zullo F, Palomba S, Zupi E, et al. Effectiveness of presacral neurectomy in women with severe dysmenorrhea caused by endometriosis who were treated with laparoscopic conservative surgery: a 1-year prospective randomized double-blind controlled trial. Am J Obstet Gynecol. 2003;189(1):5-10.

Zullo F, Palomba S, Zupi E, et al. Long-term effectiveness of presacral neurectomy for the treatment of severe dysmenorrhea due to endometriosis. J Am Assoc Gynecol Laparosc. 2004;11(1):23-28.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
10/01/2014	• Reorganized policy content • Added benefit considerations language for *Essential Health Benefits for Individual and Small Group* plans to indicate: o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs") o Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage • Updated coverage rationale: o Reformatted and relocated information pertaining to medical necessity review; added language to indicate if service is "medically necessary" or "not medically necessary" to applicable proven/unproven statement • Updated supporting information to reflect the most current description of services, clinical evidence and references • Archived previous policy version 2013T0059J