

Medical Coverage Policy



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Pelvic Denervation Procedures

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[Endometrial Ablation](#)

INSTRUCTIONS FOR USE

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Overview

This Coverage Policy addresses presacral neurectomy (PSN) and laparoscopic uterosacral nerve ablation (LUNA) which are surgical interventions for chronic pelvic pain.

Coverage Policy

Presacral neurectomy (PSN) is considered medically necessary as an alternative to hysterectomy when the available medical and surgical treatment options have failed to control refractory midline dysmenorrhea.

Laparoscopic uterosacral nerve ablation (LUNA) is considered experimental, investigational or unproven for ANY indication.

General Background

Presacral neurectomy (PSN) and laparoscopic uterosacral nerve ablation (LUNA) are neurolytic surgical interventions for chronic pelvic pain due to refractory dysmenorrhea. The procedures are sometimes done as an

adjunct to laparoscopic resection of endometriosis. LUNA involves the destruction of the pain-conducting nerve fibers that leave the uterus through the uterosacral ligaments. In PSN, the nerve bundles that transmit pain from the uterus and cervix to the spine are transected. Both procedures are thought to decrease pain by interrupting the sensory nerve pathways from the uterus and cervix. PSN is reported to be more technically challenging than LUNA, due to the presence of large blood vessels and the proximity of the ureters to the surgical field. Complications of constipation and urinary retention can follow PSN.

Chronic pelvic pain refers to menstrual or nonmenstrual pain of at least six months' duration occurring below the umbilicus. Sources of chronic pelvic pain include urological, gastrointestinal, musculoskeletal or gynecological organs. Dysmenorrhea, one of the most frequently reported gynecological problems, is characterized by sharp, intermittent spasms of pelvic pain, which may radiate to the lower back. Medical therapy for dysmenorrhea includes nonsteroidal anti-inflammatory drugs (NSAIDs) and/or oral contraceptives. Approximately 10–25% of women with dysmenorrhea do not respond to medical management and may require surgical intervention. Conservative surgical procedures, such as LUNA and PSN, aim to preserve fertility. Hysterectomy may be considered in those cases where childbearing ability does not have to be preserved.

Endometriosis is one of the most common causes of chronic pelvic pain. The disorder is characterized by the presence of functioning endometrial tissue outside of the uterus. This tissue forms lesions most commonly on the ovaries and pelvic peritoneum. These lesions are hormonally responsive, resulting in dysmenorrhea or pain that worsens just before and with menses. Other common symptoms include dyspareunia and low back pain. Progestins, androgenic agents, oral contraceptives, NSAIDs and gonadotropin-releasing hormone (GnRH) agonists have all been shown to reduce the size of endometriotic lesions (Schenken, 2023; American College of Obstetricians and Gynecologists [ACOG] 2010, reaffirmed 2022). Surgical ablation of lesions is frequently performed when the laparoscopic diagnosis of endometriosis is made. Definitive surgery, including hysterectomy and oophorectomy, is typically reserved for women who no longer desire pregnancy. LUNA and PSN have become alternative surgical options for those who choose to preserve fertility.

Literature Review - Presacral Neurectomy (PSN): A systematic review by Yeung et al. (2009) of RCTs (n=35 studies) and Cochrane analyses (n=7 reviews) evaluated laparoscopic management of endometriosis. Studies addressing LUNA included a total of three RCTs (n=298). The use of PSN was evaluated in one RCT (n=141). Laparoscopic PSN, but not LUNA, was found to be a useful adjunct to conservative surgery for endometriosis in patients with a midline component of pain.

In a Cochrane analysis, Proctor et al. (2005) reviewed a total of nine RCTs. PSN was evaluated in three RCTs (Zullo, et al., 2004; Candiani, et al., 1992; Tjaden, et al., 1990) described below. For the treatment of primary dysmenorrhea there was some evidence of the effectiveness of LUNA compared to a control or no treatment. The comparison between LUNA and laparoscopic presacral neurectomy (LPSN) showed no significant difference in pain relief in the short term; however, in the long term LPSN was shown to be significantly more effective than LUNA. It was noted that, overall, the small number of subjects participating in RCTs on LUNA and PSN make it difficult to assess the effectiveness of these procedures in treating dysmenorrhea.

Zullo et al. (2004) performed an RCT (n=141) to evaluate the long-term effectiveness of PSN for the treatment of severe dysmenorrhea due to endometriosis. Patients were randomized to receive only excision of endometriotic lesions (n=70) or excision of lesions with PSN (n=71). At 24-month follow-up, the severity of dysmenorrhea, dyspareunia and chronic pelvic pain (CPP) was significantly lower in the PSN group ($p<0.05$). The overall cure rate, defined as the percentage of patients reporting absence of dysmenorrhea or pain not requiring medical treatment, was also higher in this group ($p<0.05$).

An RCT (n=71) by Candiani et al. (1992) assigned patients with moderate or severe endometriosis and midline dysmenorrhea to conservative surgery alone (n=36) or conservative surgery and PSN (n=35). Outcome measures included relief of dysmenorrhea, pelvic pain, and deep dyspareunia after surgery according to a multidimensional and an analog pain scale. PSN was found to decrease midline pelvic pain, however no statistically significant differences were observed between the two groups in the frequency and severity of dysmenorrhea, pelvic pain, and dyspareunia in the long-term follow-up.

Tjaden et al. (1990) conducted an RCT (n=26) to evaluate the effectiveness of PSN for the treatment of midline dysmenorrhea. All patients were scheduled to undergo laparotomy for resection of endometriosis. A protocol group (n=8) was randomized to PSN or no PSN. A non-protocol or non-randomized group (n=18) consisted of patients who wanted to undergo PSN (n=13) and those who did not (n=5). Of the patients undergoing PSN (n=17), two had a recurrence of pain; the remaining patients were pain-free at 42 months of follow-up. None of the patients undergoing resection of endometriosis but not PSN (n=9) received relief of midline pain.

The published peer-reviewed medical literature contains limited evidence in the form of RCTs and systematic reviews to suggest that presacral neurectomy (PSN) may be indicated for those patients with intractable, midline pelvic pain who have failed optimal conservative treatment options.

Literature Review - Laparoscopic Uterosacral Nerve Ablation (LUNA): In a Cochrane analysis, Leonardi et al. (2021) reviewed a total of four RCTs (n=216) that assessed the effectiveness and safety of adhesiolysis or LUNA in the management of women with chronic pelvic pain syndrome (CPPS). The primary outcome measured pain scores and quality of life after surgery.

- One study examined laparoscopic adhesiolysis versus diagnostic laparoscopy without adhesiolysis.
- One study compared adhesiolysis via laparotomy versus diagnostic laparoscopy without adhesiolysis.
- Two studies compared LUNA versus an alternative diagnostic laparoscopy or vaginal uterosacral ligament resection (VUSR).

The study reported uncertainty of the effect laparoscopic uterosacral ligament ablation compared to diagnostic laparoscopy or vaginal uterosacral ligament resection had on pain scores. Pain scores were measured by visual acuity scale (VAS) at three, six and 12 months. The analysis concluded that women undergoing LUNA may require more pain relief after surgery than those undergoing alternative treatments. The evidence ranged from very low to low certainty. Noted limitations included poor reporting of study methods and imprecision (too few events, too few included studies) for some comparisons.

Andrews et al. (2012) conducted a comparative effectiveness review of CPP therapies for the Agency for Healthcare Research and Quality (AHRQ). The review of 36 studies included randomized controlled trials (RCTs) (n=18 studies), cohort (n=3 studies) and cross-sectional studies (n=15 studies). There was no evidence found in studies addressing surgical interventions (n=2 RCTs/610 subjects) that LUNA is more effective than simple diagnostic laparoscopy.

EI-Din Shawki (2011) conducted a prospective single-blind RCT (n=190) to evaluate the safety and efficacy of LUNA for CPP in women with no pathology or mild endometriosis. The control group (n=95) had diagnostic laparoscopy with no pelvic denervation and the study group had diagnostic laparoscopy plus LUNA (n=95). At 12 months of follow-up, there was no statistically significant difference between groups for efficacy, overall success rate and patient satisfaction ($p \leq 0.05$), indicating that the adjunctive use of LUNA had little benefit.

Daniels et al. (2009) conducted a patient-blinded RCT to assess the effectiveness of LUNA (n=243) compared to no denervation (n=244) in women undergoing laparoscopy for CPP. Follow-up was conducted by questionnaires at three and six months and at one, two, three, and five years (72% of participants available). After a median follow-up of 69 months, there were no significant differences between the LUNA and the no LUNA groups reported on the visual analogue pain scales for the worst pain over all time points ($p=0.80$). No differences were found between the LUNA group and the no LUNA group for quality of life. Minor hemorrhaging occurred in eight cases. Acknowledged study limitations include loss to follow-up and possibly inadequate statistical power.

Latthe et al. (2007) conducted a systematic review of the nine RCTs analyzed by Proctor et al. (2006) described below. These authors echoed the findings of a Cochrane analysis by Proctor et al. (2005) that there is limited evidence for nerve interruption procedures in the management of dysmenorrhea and that methodologically sound and sufficiently powered RCTs are needed. It was stated that “clinicians who have expertise in performing neuroablation should offer these procedures only as a last-line treatment after other conservative treatment options have been ineffective”.

An RCT (n=80) by Palomba et al. (2006) compared LUNA and vaginal uterosacral ligament resection (VUSR) in postmenopausal women with CPP. The cure rate was not found to be significantly different between the two groups at 12-month follow-up. A significant ($p<0.01$) decrease in severity of CPP and deep dyspareunia was observed in both groups suggesting equal effectiveness of the procedures. One study limitation was the absence of a control group to test the placebo effect of each surgical approach.

Johnson et al. (2004) conducted a prospective, double-blind, randomized controlled trial with 123 women to determine the effectiveness of LUNA for CPP. Women were randomized from two groups: those with endometriosis (n=67), and those with no laparoscopic evidence of endometriosis (n=56), to receive LUNA or no LUNA. The investigators reported significant reduction in dysmenorrhea at 12-month follow-up in women with CPP without a diagnosis of endometriosis who underwent LUNA ($p=0.039$).

The published RCTs, cohort, and cross-sectional studies evaluating the safety and effectiveness of laparoscopic uterosacral nerve ablation (LUNA) have yielded mixed results. The available evidence does not support the safety and efficacy of this procedure.

Professional Societies/Organizations

American Society for Reproductive Medicine (ASRM): The ASRM issued a committee opinion on the treatment of pelvic pain associated with endometriosis. According to the ASRM, PSN has been proposed for treatment of midline pain associated with menses, because its effects on other components of pelvic pain have been inconsistent. The ASRM stated that it is important to understand that PSN is a technically challenging procedure associated with significant risk of bleeding. The committee also stated that LUNA does not appear to offer any additional benefits beyond those that can be achieved with conservative surgery alone (Practice Committee of the ASRM, 2014).

American College of Obstetricians and Gynecologists (ACOG): The ACOG practice bulletin on chronic pelvic pain stated that there is limited evidence to support laparoscopic uterosacral nerve ablation and presacral neurectomy in the treatment of chronic pelvic pain. A large RCT found no improvement. Nerve interruption in the treatment of chronic pain is not supported by RCT's (ACOG, 2020; Reaffirmed 2023).

The ACOG practice bulletin on the management of endometriosis stated that PSN is effective only for midline pain. The efficacy of the LUNA done as an adjunct to surgical management of endometriosis is not supported by RCT's (ACOG, 2010; Reaffirmed 2022).

Use Outside of the US

The Society of Obstetricians and Gynaecologists of Canada (SOGC) clinical practice guidelines stated that there is some evidence that LUNA might be helpful in treating patients with dysmenorrhea when there is not any visual abnormalities during a laparoscopy. Another conservative treatment that may also be of benefit for women with primary dysmenorrhea is PSN. Furthermore, if fertility preservation is desired, uterine nerve ablation and presacral neurectomy may be done (Jarrell, et al., 2018; Burnett et al., 2017).

The National Institute for Health and Clinical Excellence (NICE) issued guidelines on the use of LUNA for chronic pelvic pain. According to the NICE overview, conservative treatment may include NSAIDs and a trial of contraceptives when the cause of the pelvic pain cannot be identified. If other treatments fail, options for surgical treatment include LUNA and PSN. The NICE overview of the procedure examined evidence in the form of case series (n=4) and case reports (n=2), one Cochrane systematic review and meta-analysis, one additional RCT, and a non-randomized comparative study. Key efficacy outcomes were pain relief and improvement in quality of life. Based on a review of this evidence, NICE has stated that currently there is uncertainty about the efficacy of LUNA for the treatment of chronic pelvic pain (NICE, 2007).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD		No National Coverage Determination found	

	Contractor	Determination Name/Number	Revision Effective Date
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met for Presacral Neurectomy (PSN):

CPT®* Codes	Description
58578	Unlisted laparoscopy procedure, uterus
64999	Unlisted procedure, nervous system

Considered Experimental/Investigational/Unproven when used to report laparoscopic uterosacral nerve ablation (LUNA):

CPT®* Codes	Description
58578	Unlisted laparoscopy procedure, uterus
64999	Unlisted procedure, nervous system

*Current Procedural Terminology (CPT®) ©2022 American Medical Association: Chicago, IL.

References

1. American College of Obstetricians and Gynecologists (ACOG). Practice Bulletin. Clinical Management Guidelines for Obstetrician-Gynecologists. Management of Endometriosis. Number 114, July 2010; Reaffirmed 2022.
2. American College of Obstetricians and Gynecologists (ACOG). Practice Bulletin. Chronic Pelvic Pain. Number 218, Obstet Gynecol. 2020 Mar;135(3):e98-e109. Reaffirmed 2023.
3. Andrews J, Yunker A, Reynolds WS, Likis FE, Sathe NA, Jerome RN. Noncyclic Chronic Pelvic Pain Therapies for Women: Comparative Effectiveness [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2012 Jan. Report No.: 11(12)-EHC088-EF. AHRQ Comparative Effectiveness Reviews.
4. Budden A, Ravendran K, Abbott JA. Identifying the Problems of Randomized Controlled Trials for the Surgical Management of Endometriosis-associated Pelvic Pain. J Minim Invasive Gynecol. 2020 Feb;27(2):419-432.
5. Burnett M, Lemyre M. No. 345-Primary Dysmenorrhea Consensus Guideline. Journal of Obstetrics and Gynaecology Canada. 2017 39(7): 585–95.
6. Candiani GB, Fedele L, Vercellini P, Bianchi S, Di Nola G. Presacral neurectomy for the treatment of pelvic pain associated with endometriosis: a controlled study. Am J Obstet Gynecol. 1992 Jul;167(1):100-3.

7. Daniels J, Gray R, Hills RK, Latthe P, Buckley L, Gupta J, et al. Laparoscopic uterosacral nerve ablation for alleviating chronic pelvic pain: a randomized controlled trial. *JAMA*. 2009 Sep 2;302(9):955-61.
8. 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.
9. Jacobson TZ, Barlow DH, Garry R, Koninckx P. Laparoscopic surgery for pelvic pain associated with endometriosis. *Cochrane Database Syst Rev*. 2001;(4):CD001300.
10. Jarrell JF, Vilos GA, Allaire C, Burgess S, Fortin C, Gerwin R, et al. No. 164-Consensus Guidelines for the Management of Chronic Pelvic Pain. *J Obstet Gynaecol Can*. 2018 Nov;40(11).
11. Johnson NP, Farquhar CM, Crossley S, Yu Y, Van Peperstraten AM, Sprecher M, 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.
12. Juang CM, Chou P, Yen MS, Horng HC, Twu NF, Chen CY. Laparoscopic uterosacral nerve ablation with and without presacral neurectomy in the treatment of primary dysmenorrhea: a prospective efficacy analysis. *J Reprod Med*. 2007 Jul;52(7):591-6.
13. Juang CM, Yen MS, Horng HC, Cheng CY, Yu HC, Chang CM. Treatment of primary deep dyspareunia with laparoscopic uterosacral nerve ablation procedure: a pilot study. *J Chin Med Assoc*. 2006 Mar;69(3):110-4.
14. Latthe PM, Proctor ML, Farquhar CM, Johnson N, Khan KS. Surgical interruption of pelvic nerve pathways in dysmenorrhea: a systematic review of effectiveness. *Acta Obstet Gynecol Scand*. 2007;86(1):4-15.
15. Leonardi M, Armour M, Gibbons T, Cave A, As-Sanie S, Condous G, et al. Surgical interventions for the management of chronic pelvic pain in women. *Cochrane Database Syst Rev*. 2021 Dec 20;12(12):CD008212. doi: 10.1002/14651858.CD008212.pub2
16. Miller LE, Bhattacharyya R, Miller VM. Clinical Utility of Presacral Neurectomy as an Adjunct to Conservative Endometriosis Surgery: Systematic Review and Meta-Analysis of Controlled Studies. *Sci Rep*. 2020 Apr 23;10(1):6901.
17. National Institute for Health and Clinical Excellence (NICE). Laparoscopic uterine nerve ablation (LUNA) for chronic pelvic pain: Guidance. October 2007. Accessed April 13, 2023. Available at URL address: <https://www.nice.org.uk/guidance/IPG234>
18. Palomba S, Russo T, Falbo A, Manguso F, D'Alessandro P, Mattei 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 Jan 24.
19. Palomba S, Zupi E, Falbo A, Russo T, Tolino A, Marconi D, et al. Presacral neurectomy for surgical management of pelvic pain associated with endometriosis: a descriptive review. *J Minim Invasive Gynecol*. 2006 Sep-Oct;13(5):377-85.
20. Practice Committee of the American Society for Reproductive Medicine. Treatment of pelvic pain associated with endometriosis: a committee opinion. *Fertil Steril*. 2014 Apr;101(4):927-35.
21. Proctor M, Farquhar C. Diagnosis and management of dysmenorrhea. *BMJ*. 2006 May 13;332(7550):1134-8.
22. Proctor ML, Latthe PM, Farquhar CM, Khan KS, Johnson NP. Surgical interruption of pelvic nerve pathways for primary and secondary dysmenorrhoea. *Cochrane Database Syst Rev*. 2005 Oct 19;(4):CD001896.

23. Ramirez C, Donnellan N. Pelvic denervation procedures for dysmenorrhea. *Curr Opin Obstet Gynecol.* 2017 Aug;29(4):225-230.
24. Schenken RS. Endometriosis: Treatment of pelvic pain. In: UpToDate, Barbieri RL (Ed). Literature review current through: March 2023. Last updated January 31, 2023. UpToDate, Waltham, MA. Accessed April 13, 2023.
25. Singh SS, Gude K, Perdeaux E, Gattrell WT, Becker CM. Surgical Outcomes in Patients With Endometriosis: A Systematic Review. *J Obstet Gynaecol Can.* 2019 Nov 9;S1701-2163(19)30730-3.
26. Tjaden B, Schlaff WD, Kimball A, Rock JA. The efficacy of presacral neurectomy for the relief of midline dysmenorrhea. *Obstet Gynecol.* 1990 Jul;76(1):89-91.
27. 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.
28. Zullo F, Palomba S, Zupi E, Russo T, Morelli M, Sena T, et al. Long-term effectiveness of presacral neurectomy for the treatment of severe dysmenorrhea due to endometriosis. *J Am Assoc Gynecol Laparosc.* 2004 Feb;11(1):23-8.

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