Medical Coverage Policy

Effective Date.....6/15/2025
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Coverage Policy Number..... 0368

Pelvic Denervation Procedures

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Related Coverage Resources

Endometrial Ablation

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

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.

El-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).

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).

Medicare Coverage Determinations

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

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
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

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• No policy statement changes	6/15/2025
Annual Review	• No policy statement changes.	6/15/2024