



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Effective Date ..... 6/15/2010  
Next Review Date ..... 6/15/2012  
Coverage Policy Number ..... 0368

Subject **Pelvic Denervation Procedures**

## Table of Contents

Coverage Policy .....	1
General Background .....	1
Coding/Billing Information .....	3
References .....	3
Policy History .....	5

## Hyperlink to Related Coverage Policies

Hysterectomy

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), 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 supercedes** 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. 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. Proprietary information of CIGNA. Copyright ©2011 CIGNA

## Coverage Policy

**CIGNA covers presacral neurectomy (PSN) for the treatment of central dysmenorrhea as medically necessary only as alternative to hysterectomy when all other conservative treatment options have failed to control refractory dysmenorrhea.**

**CIGNA does not cover laparoscopic uterosacral nerve ablation (LUNA) for the treatment of any condition because it is considered experimental, investigational or unproven.**

## General Background

Laparoscopic uterosacral nerve ablation (LUNA) and presacral neurectomy (PSN) are neurolytic surgical interventions for chronic pelvic pain (CPP) 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.

CPP refers to menstrual or nonmenstrual pain of at least six months' duration occurring below the umbilicus. Sources of CPP 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 CPP. 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 (Lapp, 2000). 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**

Daniels et al. (2009) conducted a patient-blinded randomized controlled trial (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 (Daniels, et al., 2009).

Latthe et al. (2007) conducted a systematic review of the nine RCTs analyzed by Proctor et al. (2005) 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” (Latthe, et al., 2007).

In an update to a Cochrane analysis, Proctor et al. (2005) reviewed a total of nine RCTs. 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. The review of trials found “limited evidence to support the use of LUNA and PSN for primary dysmenorrhea and little evidence for their use in women with endometriosis.” The reviewers maintained the conclusion that there is insufficient evidence to recommend the use of these procedures in the management of dysmenorrhea regardless of the cause (Proctor, et al., 2005).

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).

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 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).

### **Professional Societies/Organizations**

The National Institute for Health and Clinical Excellence (NICE) issued a guidance on the use of LUNA for CPP. 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 CPP (NICE, 2007a).

The American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin on CPP states that psychosomatic factors appear to have a prominent role in CPP, which suggests that psychiatric or psychological evaluation and treatment should be routine for women with CPP. ACOG states that PSN may be considered for treatment of central dysmenorrhea that is unresponsive to other treatment but has limited efficacy for lateral or CPP. LUNA may also be considered for midline dysmenorrhea but appears to be less effective than PSN for this indication. The combination of LUNA or PSN with surgical treatment of endometriosis does not further improve overall pain relief (ACOG, 2004).

### Summary

The published peer-reviewed medical literature contains some evidence in the form of observational studies to suggest that presacral neurectomy (PSN) may be indicated for those patients with intractable, midline pelvic pain who have failed optimal conservative treatment options. The available published evidence evaluating the use of laparoscopic uterosacral nerve ablation (LUNA) does not support the safety and efficacy of this procedure.

---

### Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**Covered when medically necessary:**

CPT <sup>®*</sup> Codes	Description
58578 <sup>†</sup>	Unlisted laparoscopy procedure, uterus

ICD-9-CM Diagnosis Codes	Description
625.3	Dysmenorrhea

<sup>†</sup>**Note:** Covered when medically necessary and used to report presacral neurectomy (PSN) for the treatment of dysmenorrhea. Experimental/Investigational/Unproven/Not Covered when used to report laparoscopic uterosacral nerve ablation (LUNA).

\*Current Procedural Terminology (CPT<sup>®</sup>) © 2010 American Medical Association: Chicago, IL.

---

### References

1. American College of Obstetricians and Gynecologists (ACOG). Practice Bulletin. Clinical Management Guidelines for Obstetrician-Gynecologists. Chronic Pelvic Pain. Number 51, March 2004.
2. 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.
3. Jacobson TZ, Barlow DH, Garry R, Koninckx P. Laparoscopic surgery for pelvic pain associated with endometriosis. Cochrane Database Syst Rev. 2001;(4):CD001300.

4. 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.
5. 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.
6. 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.
7. Lapp T. ACOG addresses psychosocial screening in pregnant women. ACOG issues recommendations for the management of endometriosis. American College of Obstetricians and Gynecologists. *Am Fam Physician*. 2000 Sep 15;62(6):1431, 1434.
8. 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.
9. National Institute for Health and Clinical Excellence (NICE). Laparoscopic uterine nerve ablation (LUNA) for chronic pelvic pain (interventional procedures overview). May 2007a. Accessed May 6, 2008. Available at URL address:  
<http://www.nice.org.uk/nicemedia/pdf/ip/376%20LUNA%20overview%20for%20web%20240507.pdf>
10. National Institute for Health and Clinical Excellence (NICE). Laparoscopic uterine nerve ablation (LUNA) for chronic pelvic pain: Guidance. October 2007b. Accessed May 6, 2008. Available at URL address:  
<http://www.nice.org.uk/nicemedia/pdf/IPG234Guidance.pdf> .
11. 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; [Epub ahead of print]
12. 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.
13. 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.
14. Proctor M, Farquhar C. Diagnosis and management of dysmenorrhoea. *BMJ*. 2006 May 13;332(7550):1134-8.
15. 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.

## Policy History

<u>Pre-Merger</u>	<u>Last Review</u>	<u>Policy</u>	<u>Title</u>
<u>Organizations</u>	<u>Date</u>	<u>Number</u>	
CIGNA HealthCare	06/15/2008	0368	Pelvic Denervation Procedures

"CIGNA", "CIGNA HealthCare" and the "Tree of Life" logo are registered service marks of CIGNA Intellectual Property, Inc., licensed for use by CIGNA Corporation and its operating subsidiaries. All products and services are provided by such operating subsidiaries and not by CIGNA Corporation. Such operating subsidiaries include Connecticut General Life Insurance Company, CIGNA Health and Life Insurance Company, CIGNA Behavioral Health, Inc., CIGNA Health Management, Inc., and HMO or service company subsidiaries of CIGNA Health Corporation and CIGNA Dental Health, Inc. In Arizona, HMO plans are offered by CIGNA HealthCare of Arizona, Inc. In California, HMO plans are offered by CIGNA HealthCare of California, Inc. In Connecticut, HMO plans are offered by CIGNA HealthCare of Connecticut, Inc. In North Carolina, HMO plans are offered by CIGNA HealthCare of North Carolina, Inc. In Virginia, HMO plans are offered by CIGNA HealthCare Mid-Atlantic, Inc. All other medical plans in these states are insured or administered by Connecticut General Life Insurance Company or CIGNA Health and Life Insurance Company.