Prior Authorization Review Panel  
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

<table>
<thead>
<tr>
<th>Plan: Aetna Better Health</th>
<th>Submission Date: 11/01/2019</th>
</tr>
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<tbody>
<tr>
<td>Policy Number: 0754</td>
<td>Effective Date: 12/05/2014</td>
</tr>
<tr>
<td>Policy Name: Uterine Nerve Ablation (UNA) and Presacral Neurectomy (PSN)</td>
<td></td>
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Type of Submission – Check all that apply:

- [ ] New Policy
- [X] Revised Policy*
- [ ] Annual Review – NoRevisions
- [ ] Statewide PDL

*All revisions to the policy must be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below:

**CPB 0754 Uterine Nerve Ablation (UNA) and Presacral Neurectomy (PSN)**

Clinical content was last revised on 12/05/2014. Additional non-clinical updates were made by Corporate since the last PARP submission, as documented below.

Update History since the last PARP Submission:

03/01/2019-This CPB has been updated with additional information and references.

Name of Authorized Individual (Please type or print): Dr. Bernard Lewin, M.D.

Signature of Authorized Individual: [Signature]

Proprietary

Revised July 22, 2019
Uterine Nerve Ablation (UNA) and Presacral Neurectomy (PSN)

Number: 0754

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers uterine nerve ablation (UNA), laparoscopic uterine nerve ablation (LUNA) and presacral neurectomy (PSN; both open and laparoscopic) experimental and investigational for the treatment of chronic pelvic pain or other indications because their effectiveness has not been established.

Background

Approximately 15 to 20% of women between 18 to 50 years of age have chronic pelvic pain of more than one year's duration. The American College of Obstetricians and Gynecologists (ACOG, 2004) defined chronic pelvic pain as non-cyclical pain of at least 6 months' duration that appears in locations such as the pelvis, anterior abdominal wall, lower back, or buttocks, and is serious enough to cause disability or lead to medical care. Chronic pelvic pain includes primary and secondary dysmenorrhea. Primary dysmenorrhea occurs in the absence of an identifiable cause, while secondary dysmenorrhea describes menstrual pain associated with a physical cause. Endometriosis is the most common gynecological cause of chronic pelvic pain. Other causes of chronic pelvic pain include pelvic inflammatory disease, pelvic congestion syndrome, nerve entrapment, interstitial cystitis, emotional stress, and pelvic floor pain related to muscular spasm.
Treatment for chronic pelvic pain depends on the underlying cause, severity of symptoms, the extent and location of disease, the desire for pregnancy, and the age of the patient. Conservative medical treatments for endometriosis include non-steroidal anti-inflammatory drugs and oral contraceptives. If these fail to relieve symptoms, second-line pharmacologics, such as danazol and gonadotropin-releasing hormone analogs, may be indicated. Conservative surgery involves excision, fulguration, or laser vaporization of endometriotic implants and removal of associated adhesions. Hysterectomy may be considered for patients with severe symptoms that do not respond to conservative treatment.

The use of nerve transection procedures have been investigated for the treatment of chronic pelvic pain. They are often carried out during the course of other surgical treatment for endometriosis. The most common of these nerve transection procedures are laparoscopic uterine nerve ablation (LUNA) and pre-sacral neurectomy (PSN). Laparoscopic uterine nerve ablation involves the destruction of the uterine nerve fibers that exit the uterus through the uterosacral ligament. Pre-sacral neurectomy refers to the interruption of the sympathetic innervation of the uterus at the level of the superior hypogastric plexus. Pre-sacral neurectomy is technically more challenging than LUNA because of the presence of large vessels and the ureters near the field of dissection.

Three randomized controlled trials (RCTs) using PSN along with other surgical treatment of endometriosis have been published (Tjaden et al, 1990; Candiani et al, 1992; Zullo et al, 2003). A RCT comparing outcomes of PSN to LUNA has also been published (Chen et al, 1996).

Tjaden et al (1990) found that the addition of PSN to standard surgical therapy by laparotomy enhanced pain relief for midline pain. However, only 8 of 26 patients were randomized and the study was terminated before completion because of significant reduction in midline pain by the patients undergoing PSN.

Candiani and colleagues (1992) randomly assigned 71 women with moderate to severe endometriosis and midline dysmenorrhea to conservative surgery alone or conservative surgery with PSN. The addition of PSN markedly reduced the midline component of menstrual pain, but no statistically significant differences were observed between the 2 groups in the frequency and severity of dysmenorrhea, pelvic pain, and dyspareunia in the long-term follow-up. Furthermore, constipation developed or worsened in 13 of 35 patients and urinary urgency developed in 3. The authors concluded that PSN should be considered only in selected cases (e.g., women with severe incapacitating dysmenorrhea, recurrent disease, or symptoms that did not respond to initial treatment).
Zullo et al (2003) randomly assigned 141 women aged 26 to 39 years with severe dysmenorrhea due to endometriosis to laparoscopic electrocautery ablation or excision, enucleation of endometriomas, lysis of adhesions, and uterosacral ligament resection of deep ligamentous lesions (group A) or these treatments plus PSN (group B). The addition of PSN significantly improved cure rates (defined as significant relief of dysmenorrhea) at both 6 months (87 % versus 60 %) and 12 months (86 % versus 57 %); the improvement occurred across all stages. Although the severity of dysmenorrhea, dyspareunia, and pelvic pain was lower in group B than group A, there was no difference between groups in the frequency of these symptoms. Surgical complications were uncommon and equivalent; constipation and urgency only occurred in women who had PSN (at 12 months: constipation 14 % and urgency 5 %). Of note, conservative surgery alone (i.e., without PSN) led to most of the reduction in severity of dysmenorrhea, as measured by a visual analog scale (VAS) (baseline score: 82, after conservative surgery: 54, after conservative surgery and PSN: 46). The authors concluded that PSN with conservative surgery was an effective treatment for pelvic pain related to endometriosis.

In a RCT of 68 patients with primary dysmenorrhea assigned to either PSN or LUNA, Chen et al (1996) reported that both groups were equal in terms of symptom relief (87.9 % versus 89.9 %), but the efficacy of PSN was better than LUNA at 12 months (81.8 % versus 51.4 %).

A Cochrane review on laparoscopic surgery for pelvic pain associated with endometriosis identified a RCT that reported positive results from a combined surgical approach of laparoscopic laser ablation, adhesiolysis, and uterine nerve ablation in women with pelvic pain associated with endometriosis. The authors concluded that since only 1 trial was identified, these results should be "interpreted with caution" (Jacobson, 2001).

An expert panel comprised of practicing gynecologists from the United States (Gambone et al, 2002) concluded that: "[t]here is some evidence that adjuvant presacral neurectomy adds benefit for midline pain, but currently, there is inadequate evidence to support the use of uterosacral nerve ablation."

Vercellini et al (2003) randomly assigned 180 women with endometriosis and pelvic pain to laparoscopic treatment of endometriosis lesions or laparoscopic treatment of endometriosis lesions plus an utero-sacral ligament resection. These investigators reported that the prevalence of recurrent dysmenorrhea was similar for both groups (approximately 28 % after 1 year and approximately 34 % after 3 years). Other studies showed the same lack of efficacy of adding LUNA to the surgical treatment of endometriosis (Sutton et al, 2001). Only 1 small clinical trial suggested any efficacy for LUNA, and that trial evaluated only patients with primary dysmenorrhea (Lichten and Bombard, 1987).
A Cochrane systematic evidence review of clinical trials on surgical interruption of pelvic nerve pathways for primary and secondary dysmenorrhea found there was only limited evidence to support the use of LUNA for primary dysmenorrhea. The comparison between LUNA and laparoscopic PSN (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. 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 suggested this may be specific to laparoscopy and for midline abdominal pain only. Adverse events were significantly more common for PSN; however, the majority were complications such as constipation, which may spontaneously improve. The authors’ concluded, "[t]here is insufficient evidence to recommend the use of nerve interruption in the management of dysmenorrhea, regardless of cause" (Proctor et al, 2005).

A Cochrane review on treatment of chronic pelvic pain in women (2005) found that "LUNA is not shown to be effective" (Stones et al, 2005).

Guidelines on chronic pelvic pain from ACOG (2004) concluded: "[a]dding uterine nerve ablation to surgical treatment of endometriosis-associated pelvic pain or dysmenorrhea does not improve the outcome of surgical treatment. No evidence demonstrates that uterine nerve ablation improves nonmenstrual chronic pelvic pain." The guidelines recommended the following: "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 transection 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."

The Society for Obstetricians and Gynaecologists of Canada clinical practice guideline (2005) stated: "[t]here is limited evidence for use of presacral neurectomy in the management of primary dysmenorrhea, the risks must be carefully weighed against the expected benefits. Laparoscopic uterosacral ligament resection has not been shown to reduce dysmenorrhea and therefore should not be advocated as a mainstream treatment option."

Guidelines from the Royal College of Obstetricians and Gynaecologists (2006) concluded: "[t]here is no evidence that laparoscopic uterine nerve ablation is necessary when ablating endometriotic lesions and laparoscopic uterine nerve ablation by itself has no effect on
dysmenorrhea associated with endometriosis. In cases that have failed to respond to conservative laparoscopic surgery, there may be a role for presacral neurectomy, especially in severe dysmenorrhoea, although the evidence is inconclusive.”

Latthe and colleagues (2007) performed a systematic review of 9 RCTs to assess the effectiveness of surgical interruption of pelvic nerve pathways. The inclusion criteria were RCTs of utero-sacral nerve ablation or PSN (both open and laparoscopic procedures) for the treatment of dysmenorrhea. The main outcome measures were pain relief and adverse effects. There were 2 trials with open PSN; all other trials used laparoscopic techniques. For the treatment of primary dysmenorrhea, LUNA at 12 months was better when compared to a control or no treatment (odd ratio [OR] 6.12; 95 % confidence interval [CI]: 1.78 to 21.03). The comparison of LUNA with PSN for primary dysmenorrhea showed that at 12 months follow-up, PSN was more effective (OR 0.10; 95 % CI: 0.03 to 0.32). In secondary dysmenorrhea, along with laparoscopic surgical treatment of endometriosis, the addition of LUNA did not improve the pain relief (OR 0.77; 95 % CI: 0.43 to 1.39), while PSN did (OR 3.14; 95 % CI: 1.59 to 6.21). Adverse events were more common for PSN. These investigators concluded that the evidence for nerve interruption in the management of dysmenorrhea is limited.

A recently published guidance on "Laparoscopic Uterine Nerve Ablation (LUNA) for Chronic Pelvic Pain" from the National Institute for Health and Clinical Excellence (NICE, 2007) concluded: "[t]he evidence on laparoscopic uterine nerve ablation (LUNA) for chronic pelvic pain suggests that it is not efficacious and therefore should not be used."

While Gambone et al (2002) concluded that patients with dysmenorrhea who have not responded to medical therapy may be offered PSN, a Cochrane systematic evidence review of clinical trials on surgical interruption of pelvic nerve pathways for primary and secondary dysmenorrhea concluded, "[t]here is insufficient evidence to recommend the use of nerve interruption in the management of dysmenorrhea, regardless of cause (Proctor et al, 2005)". In addition, Latthe’s more recent systematic review of the evidence (2007) concluded that the evidence for nerve interruption in the management of dysmenorrhea is limited. It should also be noted that the procedures reported by Candiani et al (1992) and Zullo et al (2003) were performed by a single, highly experienced surgeon, which limited the generalizability of their findings.

Thus, methodologically sound and sufficiently powered RCTs are needed to assess the effectiveness of both LUNA and PSN for chronic pelvic pain in women.
In a RCT, Daniels et al (2009) evaluated the effectiveness of LUNA in patients with chronic pelvic pain. A total of 487 women with chronic pelvic pain lasting longer than 6 months without or with minimal endometriosis, adhesions, or pelvic inflammatory disease were included in this study. Follow-up was carried out by questionnaires mailed at 3 and 6 months and at 1, 2, 3, and 5 years. Patients received bilateral LUNA or laparoscopy without pelvic denervation (no-LUNA); participants were blinded to the treatment allocation. The primary outcome was pain, which was assessed by a VAS. Data concerning the 3 types of pain (non-cyclical pain, dysmenorrhea, and dyspareunia) were analyzed separately as was the worst pain level experienced from any of these 3 types of pain. 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 visual analog pain scales for the worst pain (mean difference between the LUNA group and the no-LUNA group, -0.04 cm [95 % CI: -0.33 to 0.25 cm]; p = 0.80), non-cyclical pain (-0.11 cm [95 % CI: -0.50 to 0.29 cm]; p = 0.60), dysmenorrhea (-0.09 cm [95 % CI: -0.49 to 0.30 cm]; p = 0.60), or dyspareunia (0.18 cm [95 % CI: -0.22 to 0.62 cm]; p = 0.40). No differences were observed between the LUNA group and the no-LUNA group for quality of life. The authors concluded that 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.

Jedrzejczak et al (2009) assessed and compared the effectiveness of PSN in the presence and absence of endometriosis. A total of 23 women with midline chronic pelvic pain (aged 30.3 +/- 7.9 years, range of 21 to 46) unresponsive to medical therapy were recruited to the study. Endometriosis was absent in 7 and present in 16 subjects. Laparoscopic PSN using a harmonic scalpel was performed in all subjects; simultaneous excision of endometriotic lesions was also performed in subjects with endometriosis. Intensity of dysmenorrhea and pelvic pain was measured by visual analog pain scale at 3 and 12 months post-operatively. Dysmenorrhea decreased at 3 months by 75 % (p = 0.018) in those without endometriosis and by 78 % (p = 0.001) in those with endometriosis. At 12-month, dysmenorrhea increased in women with endometriosis (p = 0.008), but not in those without endometriosis. Pelvic pain not related to menses decreased by 67 % (p = -0.0007) and by 87 % (p = 0.028), respectively, in women with and without endometriosis. Dyspareunia, declined dramatically at 3 and 12 months to a median score of 0 (the majority of subjects had no discomfort; p < 0.001); the change in dyspareunia between 3 and 12 months was in favor of patients without endometriosis (p = 0.02). The authors concluded that PSN using a harmonic scalpel results in long-term pain relief, especially in patients without endometriosis. The findings of this small study need to be validated by well-designed studies.
A review of treatments for endometriosis in Clinical Evidence (Ferrero et al, 2009) found that LUNA alone or PSN alone or with removal of endometriotic deposits is of unknown effectiveness. The review found that removal of endometrial deposits plus LUNA was more effective than diagnostic laparoscopy, but LUNA plus removal of endometriotic deposits was not more effective than removal of endometriotic deposits alone.

An UpToDate review on “Treatment of chronic pelvic pain in women” (Howard, 2014) states that “there is evidence that LUNA is not effective in the treatment of CPP and more evidence is needed before LPSN can be recommended for treatment of CPP”.

Noor and Garely (2015) noted that chronic pelvic pain (CPP) is a commonly encountered condition that often is multi-factorial. Etiologies include gynecologic, urologic, gastro-intestinal, and neurologic conditions. Laboratory tests, imaging, and surgical intervention are not always helpful in identifying the etiology of pelvic pain. For appropriate management of this complex disease process, a detailed history and physical examination, and a multi-disciplinary approach are needed. Pelvic pain may be caused by endometriosis, pelvic inflammatory disease, adenomyosis, interstitial cystitis/painful bladder syndrome, or other factors. Evaluation may include keeping a pain diary; laboratory tests, such as a pregnancy test, urinalysis, or tests for sexually transmitted infections; ultrasonography of abnormalities detected on physical examination; and laparoscopy. Specific 1st-line treatments include non-steroidal anti-inflammatory drugs (NSAIDs) and oral contraceptives for endometriosis; progestins, gonadotropin-releasing hormone (GnRH) analogs, aromatase inhibitors, or hysterectomy for adenomyosis; and education, food avoidance, and behavioral modifications for interstitial cystitis/painful bladder syndrome. Surgical options include nerve transection procedures, LUNA, and PSN, although data on effectiveness are limited.

Speer and colleagues (2016) stated that CPP in women is defined as persistent, non-cyclic pain perceived to be in structures related to the pelvis and lasting more than 6 months. Often no specific etiology can be identified, and it can be conceptualized as a chronic regional pain syndrome or functional somatic pain syndrome. It is typically associated with other functional somatic pain syndromes (e.g., irritable bowel syndrome, non-specific chronic fatigue syndrome) and mental health disorders (e.g., post-traumatic stress disorder, depression). Diagnosis is based on findings from the history and physical examination. Pelvic ultrasonography is indicated to rule out anatomic abnormalities. Referral for diagnostic evaluation of endometriosis by laparoscopy is usually indicated in severe cases. Curative treatment is elusive, and evidence-based therapies are limited. Patient engagement in a biopsychosocial approach is recommended, with treatment of any identifiable disease process such as endometriosis, interstitial cystitis/painful bladder syndrome, and co-morbid depression. Potentially beneficial medications include depot medroxyprogesterone, gabapentin, NSAIDs, and GnRH agonists with
add-back hormone therapy. Pelvic floor physical therapy may be helpful. Behavioral therapy is an integral part of treatment. In select cases, neuromodulation of sacral nerves may be appropriate. Hysterectomy may be considered as a last resort if pain appears to be of uterine origin, although significant improvement occurs in only about 50% of cases. The authors stated that CPP should be managed with a collaborative, patient-centered approach; LUNA and PSN were not mentioned as therapeutic options.

Flyckt and colleagues (2017) noted that surgical approaches to endometriosis patients with chronic pelvic pain are multi-modal and require individualization. Laparoscopic approaches are preferred over laparotomy when conservatively treating endometriosis via excision or ablation/fulguration of lesions. The available data support cystectomy over fenestration or fulguration for endometriomas; however, there may be associated decreases in ovarian reserve with endometrioma treatment. Pre-sacral neurectomy may be useful in patients with midline pain and LUNA is not effective for the treatment of pelvic pain related to endometriosis.

Appendectomy may be considered prophylactically at the time of the surgery for pelvic pain, although more studies are needed. For deep infiltrating endometriosis, the risks of aggressive bowel surgery must be weighed against the benefits of clear pain reduction. Post-operative medical suppressive therapy is strongly recommended to prolong symptom-free intervals of this chronic disease. As definitive therapy, hysterectomy can be helpful especially when combined with endometriosis excision. When performing hysterectomy, bilateral oophorectomy should be given careful consideration, as this procedure leads to premature surgical menopause and may not decrease the possibility of re-operation and persistence of symptoms in patients aged 30 to 39 years with chronic pain.

Currently, there is insufficient evidence regarding the effectiveness of open UNA for the treatment of dysmenorrhea. Well-designed studies with long-term follow-up are needed to ascertain the effectiveness of open UNA for the treatment of chronic pelvic pain or other indications.

Api and colleagues (2017) examined the correlation between the number of excised neural fibers and degree of pain relief following LPSN. In this before and after study, a total of 20 patients with severe mid-line dysmenorrhea (VAS greater than 80 mm) unresponsive to medical therapy were consecutively enrolled; all patients underwent LPSN. The superior hypogastric plexus was excised and sent for histologic confirmation. Two pathologists counted the number of neural fibers in the surgically removed tissue; VAS was used for pain assessment before and 2nd, 3rd, 6th, and 12th months after the operations. Of the initial 20 participants undergoing LPSN, 8 were excluded from the final analysis due to intra-operative diagnosis of endometriosis; therefore, the remaining 12 patients were evaluated. The pain scores significantly decreased at each follow-up visit compared with the pre-operative period (p = 0.002). The pathologists, who
were blinded, reported the median (minimum-maximum) neural fiber count as 46 (20 to 85) and 47 (18 to 83). No significant correlation was demonstrated between the number of excised neural fibers and the amount of pain relief following LPSN. The authors concluded that LPSN was an effective surgical procedure to control primary dysmenorrhea. Moreover, these researchers stated that these preliminary findings revealed that the degree of pain relief in cases of severe mid-line dysmenorrhea was not related to the amount of excised neural tissue in LPSN. They stated that the pathophysiology of pain transmission and perception, and the underlying mechanism of the effectiveness of neurectomy need to be further elucidated. This study had 2 main drawbacks. First, the hypothesis was tested in a small number of cases (n = 12); second, the subtypes of the neural fibers were not differentiated.

An UpToDate review on “Treatment of chronic pelvic pain in women” (Tu and As-Sanie, 2018) states that “Women with CPP that is refractory to the above non-pharmacologic and medical therapies often ask about surgical options to reduce their pain. Potential procedures include presacral neurectomy, lysis of adhesions, and hysterectomy. Data supporting a role of these surgeries for the treatment of CPP are limited. For each of these surgeries, we counsel women about the risk of continued pain, and new postsurgical pain, in addition to the standard surgical risks”.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+".

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<th>Code</th>
<th>Code Description</th>
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<td>There are no specific codes for Uterine Nerve Ablation (UNA), Laparoscopic Uterine Nerve Ablation (LUNA) or Presacral Neurectomy (PSN):</td>
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<td>Other HCPCS codes related to the CPB:</td>
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<td>C1886</td>
<td>Catheter, extravascular tissue ablation, any modality (insertable)</td>
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<td>ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):</td>
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<td>R10.30 - R10.33</td>
<td>Abdominal, pelvic and perineal pain</td>
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The above policy is based on the following references:


23. University of Texas at Austin, School of Nursing, Family Nurse Practitioner Program. An evidence based practice guideline for the treatment of primary dysmenorrhea. Austin, TX: University of Texas at Austin, School of Nursing; 2010.


29. Tu FF, As-Sanie S. Treatment of chronic pelvic pain in women. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed June 2018.
Amendment to
Aetna Clinical Policy Bulletin Number: 0754
Uterine Nerve Ablation (UNA) and Presacral Neurectomy (PSN)

There are no amendments for Medicaid.