Pudendal Nerve Decompression

Number: 0805

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

Aetna considers pudendal nerve decompression experimental and investigational for the treatment of following indications (not an all-inclusive list) because its effectiveness has not been established.

- Chronic pelvic pain
- Interstitial cystitis
- Persistent genital arousal disorder
- Pudendal neuralgia (also known as Alcock canal syndrome, pudendal canal syndrome, pudendal nerve entrapment, and pudendal nerve neuropathy)
- Vulvodynia/vulvar vestibulitis.

Aetna considers pudendal nerve block in the treatment of pudendal neuritis experimental and investigational because there is no clinical evidence to support the use of pudendal nerve block in the treatment of pudendal neuritis. Note: This policy does not apply to the use of pudendal nerve blocks in obstetrics and other operative procedures.

See also CPB 0759 - Vulvodynia and Vulvar Vestibulitis
Background

The pudendal nerve is a nerve in the pelvic region that carries both sensory and motor fibers; it innervates the external genitalia of both sexes, as well as sphincters for the bladder and the rectum. Pudendal neuralgia (PN), also known as Alcock canal syndrome, pudendal canal syndrome (PCS), pudendal nerve entrapment (PNE) and pudendal nerve neuropathy, is a type of neuropathic pain in the pelvic region. It is a poorly recognized disease/syndrome; and its prevalence is unknown. The International Pudendal Neuropathy Association estimates the incidence of this condition to be 1/100,000; however, most practitioners treating patients with this condition feel the actual rate of incidence may be significantly higher (Hibner et al, 2010). PN may produce anal, penile, perineal, scrotal, vaginal or vulvar (including vulvodynia) pain. The principal feature of PN is severe, sharp pain along the course of the pudendal nerve or its branches, often aggravated with sitting. The most common cause of PN is mechanical compression resulting in entrapment of the pudendal nerve, although it may also be caused by an inflammation of the nerve.

PN is sometimes referred to as cyclist syndrome because the first documented individuals with the condition were competitive cyclists. The most common profile of a patient with PN is one who had visited multiple physicians and failed multiple pharmacotherapies; with no evidence of organ disease; and had normal colorectal and uro-gynecological evaluations. The cause of the PN is not always clear, but it is believed that neuronal injury caused by compression or stretching is the key etiology. Moreover, the clinical signs and symptoms of the PN exhibit great individual variability. Pudendal neuralgia is thought to be a diagnosis of exclusion and requires a high index of suspicion.

Labat and colleagues (2008) stated that there are no pathognomonic criteria for the diagnosis of PN, however, various clinical features can be suggestive of the diagnosis.
These researchers used the Nantes criteria to aid in diagnosis; and the 5 essential diagnostic criteria are: (i) pain in the anatomical territory of the pudendal nerve, (ii) pain worsened by sitting, (iii) the patient is not woken at night by the pain, (iv) no objective sensory loss on clinical examination, and (v) positive anesthetic pudendal nerve block. Exclusion criteria include exclusive pruritus, exclusively paroxysmal pain, purely coccygeal, gluteal, or hypogastric pain, as well as presence of imaging abnormalities that are able to explain the symptoms. The authors concluded that the diagnosis of PN is essentially clinical. There are no specific clinical signs or complementary test results of this disease. However, a combination of criteria can be suggestive of the diagnosis.

Stav et al (2009) reviewed the role of PN among women with chronic pelvic pain. These investigators stated that clinical neurophysiology tests have low diagnostic efficacy and must therefore be considered to be complementary investigations. They stated that PN does seem to exist as a clinical syndrome rather than a specific diagnosis. It is important to note that it does not have definite etiological implications, and there is no evidence to support equating the presence of this syndrome with a diagnosis of PNE although that may be one etiological condition. In a European Association of Urology (EAU)’s practice guideline on chronic pelvic pain, Fall et al (2008a) stated that pudendal nerve neuropathy is likely to be a probable diagnosis if the pain is unilateral, has a burning quality and is exacerbated by unilateral rectal palpation of the ischial spine, with delayed pudendal motor latency on that side only. However, such cases account for only a small proportion of all those presenting with perineal pain. Proof of diagnosis rests on pain relief following local anesthetic nerve blocks or decompression of the nerve in Alcock’s canal, but long-term pain relief is rarely achieved.

Current treatments for PN entails behavioral modifications, pharmacotherapies (e.g., analgesics, anti-depressants, and anti-epileptics), physical therapy, pudendal nerve infiltration, nerve blocks, and decompression surgery. Pudendal nerve
block/injection is a minimally invasive procedure in which a steroid and a local anesthetic are injected into the pudendal space under imaging guidance (ie, fluoroscopy, ultrasound or computed tomography (CT) scan) to anesthetize the pudendal nerve and purportedly relieve pain in individuals with PN.

Radiofrequency ablation/denervation is destruction of nerves using heat generated by an electric current. The goals of denervation, theoretically, are to "shut off" the pain signals that are sent to the brain from the pudendal nerve and reduce the likelihood of, or to delay, any recurrence that may occur by selectively destroying pain fibers without causing excessive sensory loss, motor dysfunction or other complications.

Pudendal nerve decompression is proposed as treatment for individuals with entrapment of the pudendal nerve resulting in intractable pain and other symptoms not relieved by conservative medical therapy. The pudendal nerve can be accessed via several surgical approaches: transgluteal, transischiorectal, transperineal or laparoscopic. The transgluteal approach is a surgical approach across the gluteus maximus (the large muscle of the buttocks) and the ischial tuberosity (the bony projection on the lower back part of the hip bone, where the body rests when in a sitting position). The transischiorectal approach is a surgical approach via a vertical vaginal incision into the pararectal space in women; in men it is via a paramedian transverse perineal incision, with entrance into the pararectal space. The transperineal approach is a surgical approach via the perineum, which is the region of the body between the anus and the scrotum or vulva.

Benson and Griffis (2005) noted that improvement is gained with conservative therapy; injections and decompression benefit one-half and one-third of patients with PN, respectively. On the other hand, Tubbs et al (2009) stated that pudendal nerve block and surgical decompression are often not effective. In addition, Rhame and colleagues (2009) stated that the ideal management for PN has not been determined. Carmel and associates (2010) noted that refractory chronic
pelvic-perineal pain is a challenging entity that has devastating consequences for patients' quality of life. Many etiologies have been proposed including PN. Multiple treatment options are employed; but the reported results are sub-optimal and temporary. Hibner and colleagues (2010) stated that there is fair paucity of medical literature and scientific evidence in the diagnosis and treatment of PN. Furthermore, the EAU's clinical guideline on the general treatment of chronic pelvic pain (Falls et al, 2008b) did not mention pudendal nerve decompression (PND) as a therapeutic option.

Mauillon and associates (1999) examined if clinical symptoms, electrophysiological investigations, and the effectiveness of pre-operative pudendal nerve blocks could be used to predict the effectiveness of PND in patients with PN. A total of 12 consecutive patients complaining of anal pain, genital pain, or both, exacerbated in the sitting position and unsuccessfully treated by analgesics were studied. In these 12 patients, PND was performed following unsuccessful CT-guided injection of corticosteroids in the pudendal nerve at the ischial spine or after pain relapse following successful injections. A total of 19 nerves were decompressed by surgery, and the compressed area was located between the sacro-spinal and sacro-tuberal ligaments for 18 nerves. Three months after surgery, 4 patients were totally relieved, and 3 were only partially improved. After 21 months of follow-up, 3 patients were cured, 1 was slightly improved, and 8 remained in pain. In the 3 patients cured by surgery, pain completely disappeared for at least 2 weeks after a nerve block repeated twice before surgery, whereas pain relief was observed in only 1 of the 9 other patients \((p = 0.018)\). None of the 3 patients cured by surgery was being treated for depression, whereas 6 of the 9 remaining patients were receiving antidepressants or were followed by a psychiatrist \((p = 0.09)\). Results of surgery did not depend on other pre-operative clinical or electrophysiological data. The authors concluded that this preliminary study suggested that complete disappearance of pain for at least 2 weeks after a nerve block repeated twice before surgery may be the best criterion to predict success.
In a case series study, Bautrant and colleagues (2003) reported their findings on the treatments of PN including infiltration therapy and surgical decompression. Over a 4-year period, the diagnosis of PN was confirmed by electrophysiological investigations in 212 subjects. These researchers rejected 12 patients because of a radiculo-medullary organic etiology. This study only reported cases of women with a peripheral pudendal nerve injury (n = 200). Thirty-eight neuropathies free of canal symptoms (obstetrical, post-traumatic) were treated by infiltration therapy. The study of a total of 162 canal syndromes showed prevalent injury at the sacro-spino-tuberal ligamental grip, which was observed in 68% of the cases, compared to the Alcock canal, which was present in only 20% of the cases. A total of 104 patients underwent surgical decompression via a trans-ischio-rectal approach after failure of the infiltration therapy. The authors reported that the short-term (1 year) results appeared to be successful -- 86% of the patients were symptom-free or with a significant reduction of pain.

Beco and colleagues (2004) noted that perineodynia (perineal pain, proctalgia, and vulvodynia), as well as anal and urinary incontinence are the main symptoms of the PCS or PNE. These researchers examined the effect of bilateral PND on the symptoms of PCS, on 3 clinical signs (i.e., abnormal sensibility, painful Alcock's canal and painful "skin rolling test"), and on 2 neurophysiological tests (i.e., electromyography and pudendal nerve terminal motor latencies [PNTML]). Patients were evaluated before and at least 1 year after surgery. When bilateral PND was the only procedure done to treat the symptoms, the cure rates of anal incontinence, perineodynia, and urinary incontinence were 4/5 (80%), 8/14 (57%), and 3/5 (60%), respectively. The frequency of the 3 clinical signs was significantly reduced. There was a significant reduction of anal and perineal pudendal nerve terminal motor latencies and a significant increase of anal richness on electromyography. The authors concluded that these findings suggested that bilateral PND can treat perineodynia, as well as anal and urinary incontinence. Moreover, they stated that there is a need for further studies to confirm these preliminary results.
In a randomized, controlled trial, Robert and associates (2005) compared PND with non-surgical treatment in treating patients with PN. Patients aged 18 to 70 years and who had chronic, uni/bilateral perineal pain, positive temporary response to blocks at the ischial spine and in Alcock's canal were included. They were randomly assigned to surgery (n = 16) and control (n = 16) groups. Primary end point was improvement at 3 months following surgery or assignment to the non-surgery group. Secondary end points were improvement at 12 months and at 4 years following surgical intervention. A significantly higher proportion of the surgery group was improved at 3 months. On intention-to-treat analysis, 50% of the surgery group reported improvement in pain at 3 months versus 6.2% of the non-surgery group (p = 0.0155); in the analysis by treatment protocol the figures were 57.1% versus 6.7% (p = 0.0052). At 12 months, 71.4% of the surgery group compared with 13.3% of the non-surgery group were improved (p = 0.0025). Only those randomized to surgery were evaluated at 4 years: 8 remained improved at 4 years. No complications were encountered. The authors concluded that PND is an effective and safe treatment for cases of chronic PN that have been unresponsive to analgesics and nerve blocks. They also noted that following surgery, other medical interventions may be necessary.

Popeney et al (2007) evaluated PNE as an etiology of chronic perineal pain and clinical response to PND. A case series of 58 consecutive patients with a diagnosis of PNE, based on clinical factors, neurophysiological studies, and response to pudendal nerve infiltrations, was described. All patients were refractory to other treatment modalities. Patients were assessed before and after PND: degree of pain was assessed by visual analog scale (VAS) score, percent global overall improvement, and improved function and quality of life before surgery and 12 months or longer after surgery. The primary presenting feature was chronic, progressive, intractable neuropathic pain in the perineum that worsened with sitting. Other symptoms included constipation/painful bowel movements, sexual dysfunction, as well as urinary hesitancy, frequency, and
urgency. After surgical decompression, 35 (60 %) patients were classified as responders, based on 1 of the following 3 criteria: (i) a greater than 50 % reduction in VAS score, (ii) a greater than 50 % improvement in global assessment of pain, or (iii) a greater than 50 % improvement in function and quality of life. The authors concluded that PNE can be a cause of chronic, disabling perineal pain in both men and women. For patients refractory to conventional interventions, PND can improve pain‐related symptoms and disability. They stated that PNE is difficult to accurately diagnose and treat; with ongoing work on this subject, a better awareness of this syndrome across specialties will emerge.

Vulvodynia is chronic pain in the area around the opening of the vagina (vulva) for which there is often no identifiable cause. Shafik (1998) reported the findings of 11 women (aged 28 to 53 years) with idiopathic vulvodynia who were treated with PND. The vulvar pain was associated with stress urinary incontinence in 6/11 women and all subjects had constipation. Perineal and vulvar hypoesthesia occurred in 6; weak anal reflex in 7; and reduced electromyographic activity of the external anal sphincter in 3, of the external urethral sphincter in 6, and of the levator ani muscle in 11. There were significant increases of PNTML in all subjects (p < 0.05). The motor and sensory change as well as the increased PNTML point to PCS. Pudendal nerve block, as a diagnostic and therapeutic test, effected temporary pain relief. Pudendal nerve decompression was performed. The inferior rectal nerve was exposed through a para‐anal incision, and followed to the pudendal nerve in the pudendal canal. Pudendal canal fasciotomy was done to release the pudendal nerve in the ischiorectal fossa. Vulvar pain disappeared in 9/11 women and stress urinary incontinence in 4/6 women. Anal reflex was normalized in 5/7 subjects, and vulvar and perineal hypoesthesia in 4/6 subjects. Improved electromyographic activities were seen in the external urethral sphincter in 4/6, in the external anal sphincter in 2/3, and in the levator ani in 9/11. The PNTML was normalized in 9/11 women. The author concluded that PND provided relief and improvement in the sensory and motor manifestations of the pudendal nerve in
9/11 women. This was a small, uncontrolled study with no follow-up evaluations.

Erdogru et al (2014) examined the effectiveness of laparoscopic pudendal nerve decompression and transposition (LaPNDT) in the treatment of chronic pelvic pain due to PN. Pudendal nerve entrapment (PNE) between the sacrospinous and sacrotuberous ligaments is the most frequent etiology. These researchers described the technical details, feasibility, and advantages of a laparoscopic approach in patients with PNE. Consecutive patients (n = 27) with a diagnosis of PNE underwent LaPNDT with omental flap protection in an effort to prevent re-fibrosis around the nerve in the long-term. The degree of pain and pain impact were evaluated pre- and post-operatively using the VAS and the Impact of Symptoms and Quality of Life. The mean (± standard deviation [SD]) follow-up of the 27 patients was 6.8 ± 4.2 months; 16 of the 27 were followed-up for more than 6 months. The mean (SD) operation time was 199.4 ± 36.1 (155 to 300) mins, and the mean estimated blood loss was 39.7 ml. All patients were ambulated on the first post-operative day, and the mean (SD) hospitalization time was 2.1 ± 1.0 (1 to 6) days. The mean VAS scores of 27, 23, 16, and 6 patients were 1.5, 1.4, 1.6, and 2.0, post-operatively, at the 1st, 3rd, 6th, and 12th months (p < 0.0001). A greater than 80 % reduction in VAS score was achieved in 13 of the 16 patients (81.2 %) who were followed-up for more than 6 months. The authors concluded that LaPNDT seems a feasible surgical modality for cautiously selected patients with PNE. In addition, using an omental flap for protection of the nerve is one of the most important technical advantages of laparoscopy. Moreover, they stated that as a minimally invasive surgery, the laparoscopic approach can be technically feasible, with its promising preliminary results in the treatment of PNE. With further analysis, in the future it may open new frontiers for pudendal nerve neuromodulation as a new treatment modality in some intractable functional problems of the genito-urinary tract.

In summary, there is limited evidence on the effectiveness of
pudendal nerve decompression in the treatment of chronic pelvic pain, pudendal neuralgia, as well as vulvodynia/vulvar vestibulitis. Furthermore, many studies were also limited by small sample sizes and short-term follow-up. Well-designed studies are needed to ascertain the clinical value of pudendal nerve decompression.

*Interstitial Cystitis and Persistent Genital Arousal Disorder:*

Armstrong and Vancaillie (2016) noted that a variety of neuromodulation approaches have been described for the management of pelvic neuropathies, including interstitial cystitis, pudendal neuralgia and persistent genital arousal disorder. The benefits of a combined sacral and pudendal nerve neuromodulator has yet to be explored for these patients. These researchers described the case of a 35-year old woman with a complex pelvic neuropathy resulting in urinary, sexual and gastro-intestinal dysfunction. She presented with an established diagnosis of interstitial cystitis; however, she also fulfilled diagnostic criteria for pudendal neuralgia and persistent genital arousal disorder. The patient underwent implantation of a combined sacral and pudendal nerve neuromodulation device at the time of surgical decompression of the pudendal nerves. An impressive clinical response followed. The authors concluded that this case demonstrated a unique clinical presentation and highlighted the value of a combined surgical and neuromodulatory approach in the management of patients with complex pelvic neuropathies. The clinical value of these approaches (decompression of the pudendal nerves, as well as sacral and pudendal nerve neuromodulation) needs to be examined in well-designed studies.

Furthermore, an UpToDate review on “Management of interstitial cystitis/bladder pain syndrome” (Clemens, 2017) does not mention pudendal nerve decompression as a management tool.
ICD-10 codes will become effective as of October 1, 2015

CPT codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>64430</td>
<td>Injection, anesthetic agent; pudendal nerve</td>
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<td>64722</td>
<td>Decompression, unspecified nerve(s) (specify)</td>
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ICD-10 codes not covered for indications listed in the CPB (not an all inclusive list):

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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>G58.9</td>
<td>Mononeuropathy, unspecified [pudendal nerve entrapment]</td>
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<td>M54.10 - M54.18</td>
<td>Radiculopathy [pudendal]</td>
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<tr>
<td>M79.2</td>
<td>Neuralgia and neuritis, unspecified [pudendal]</td>
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<td>N94.810 - N94.819</td>
<td>Vulvodynia [vulvar vestibulitis]</td>
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<td>R10.2</td>
<td>Pelvic and perineal pain [chronic]</td>
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</tbody>
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The above policy is based on the following references:

4. Beco J, Climov D, Bex M. Pudendal nerve decompression


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0805
Pudendal Nerve Decompression

There are no amendments for Medicaid.

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