AETNA BETTER HEALTH®

Clinical Policy Bulletin:
Vulvodynia and Vulvar Vestibulitis Treatments

Revised April 2014

Number: 0759

Policy

Aetna considers the following treatments medically necessary for members with vulvodynia/vulvar vestibulitis:

- Physical therapy
- Perineoplasty
- Vestibulectomy (local or total) for persons who have failed conservative measures (including vulvar care, physical therapy, pharmacotherapy including analgesics).

Aetna considers the following treatments experimental and investigational for members with vulvodynia/vulvar vestibulitis because their effectiveness for this indication has not been established:

- Acupuncture
- Aromatherapy
- Botulinum toxin
- Hypnotherapy
- Laser therapy/surgery
- Palmitoylethanolamide
- Peripheral subcutaneous vulvar field stimulation
- Pelvic floor biofeedback
- Photodynamic therapy
- Pudendal nerve decompression
Vulvodynia and Vulvar Vestibulitis Treatments

Pulsed radiofrequency therapy
Sacral neuromodulation
Spinal cord stimulation
Topical baclofen
Topical nifedipine
Transcranial direct current stimulation
Vaginal acupressure (Hippocratic pelvic massage)
Vestibuloplasty.

**Background**

Vulvodynia refers to chronic vulvar discomfort including burning, stinging, irritation, or rawness for more than 3 months without other dermatological or gynecological causes. According to the International Society for the Study of Vulvovaginal Disease, the classification of vulvodynia is based on the site of the pain, whether it is localized or generalized; and whether the pain is provoked, unprovoked, or mixed. Although the term "vulvar dysesthesia" has been employed previously, there is now consensus to use the term vulvodynia and sub-categorize it as localized or generalized (Moyal-Barracco and Lynch, 2004; ACOG, 2006). The prevalence of vulvodynia is estimated to range from 3% to 18% (Bachmann et al, 2006; Gunter, 2007). Despite its high prevalence and associated distress, the pathophysiology, diagnosis and clinical management of vulvodynia have not been clearly delineated. Diagnosis is usually made after a detailed medical history has been taken, infectious or dermatological abnormalities has been ruled out, and pain is elicited in response to light pressure on the labia, introitus, or hymenal remnants. It is difficult to discern if localized vulvodynia (previously known as vestibulitis) and generalized vulvodynia are different manifestations of the same disease process since the etiology of vulvodynia is still unclear. The former can be differentiated from the latter by means of the cotton swab test.

While many therapeutic interventions have been used in the management of patients with vulvodynia, the scientific evidence for many of these therapies is incomplete. There is a scarcity of randomized controlled studies of vulvodynia treatments, which include acupuncture, cognitive behavioral therapy (CBT), electrical stimulation of the sacral nerves (i.e., sacral neuromodulation), local treatments (e.g., topical or injected steroids), pelvic floor biofeedback, pharmacotherapy including anticonvulsants, selective serotonin reuptake inhibitors, and tricyclic antidepressants (TCAs), physical therapy (PT) and surgery. New approaches include botulinum toxin, hypnotherapy, multidisciplinary pain/management program, as well as photodynamic therapy.

Hartmann et al (2007) identified current practice trends of physical therapists in the United States treating women with localized, provoked vulvodynia (LPV). A survey inquiring about PT care of women diagnosed with LPV was conducted. It queried clinicians' demographics, physician/clinician referral patterns, assessment/treatment modalities and length of care. Nearly 2/3 reported over 11 years of PT experience, with 42% treating women with vulvodynia for more than 6 years. Most referrals were from obstetricians/gynecologists. Assessment modalities used by over 70% included thorough medical history; assessment of posture, tension in the pelvic floor, pelvic girdle, associated pelvic structures and bowel/bladder function; electromyography (EMG) of the pelvic floor; hip, sacroiliac
joints and spine mobility; strength testing of abdominal muscles and lower extremities; and voiding diaries. Nearly 70% utilized exercise for the pelvic girdle and pelvic floor; soft tissue mobilization/myofascial release of the pelvic girdle, pelvic floor and associated structures; joint mobilization/manipulation; bowel/bladder retraining and help with contact irritants, dietary changes and sexual function. Typical care is 60-min weekly sessions for 7 to 15 weeks. The authors concluded that 63% of physical therapists in the United States treating women with LPV have over 11 years of experience, with almost 50% treating women for over 6 years. Obstetricians/gynecologists are the largest referral source. Three-quarters agree on 14 assessment tools, while more than 2/3 agree on 11 treatments. Women are treated weekly for 1 hour, for 7 to 15 weeks. Furthermore, in an observational study (n = 111), Goetsch (2007) stated that PT is an important adjunct to surgery in the management of patients with vulvar vestibulitis.

Glazer (2000) ascertained the long-term follow-up status of dysesthetic vulvodynia patients who were asymptomatic at the termination of treatment using surface EMG-assisted pelvic floor muscle rehabilitation (n = 62). Forty-three of these patients responded to a survey requesting information on their pain, maintenance activities and treatments, daily functioning and sexual status since treatment termination. Thirty-eight of the 43 patients (88.4%) reported experiencing no vulvar pain since completion of treatment; 3 patients reported a single episode of pain, and 2 patients reported 2 episodes each. All 5 of these patients reported the absence of any vulvar pain for a mean period of 19.8 months prior to completion of the survey. All of the 43 dysesthetic vulvodynia patients studied reported being pain-free a mean of 39.5 months after successful treatment termination. No vulvar pain-related treatments or significant restrictions on daily activities were reported. All patients reported sexual interest, pleasure and activity.

Mckay and colleagues (2001) assessed the effectiveness of EMG biofeedback of pelvic floor musculature in the management of patients with moderate-to-severe vulvar vestibulitis syndrome (VVS). A total of 29 patients were included in this study. Each patient was given a computerized EMG assessment of pelvic floor muscles. She was then provided with a portable EMG home trainer biofeedback device, and specific instructions were given to perform biofeedback-assisted pelvic floor muscle rehabilitation exercises. Patients received monthly evaluations of the pelvic floor muscles to ensure and motivate compliance and to monitor improvement and symptom changes. Patients were evaluated on a monthly basis for vestibulodynia and dyspareunia. Fifteen of the 29 treated patients (51.7%) demonstrated markedly decreased introital tenderness, and 14 of them (93.3%) were able to resume sexual activity without discomfort. Nine patients (31.0%) demonstrated a significant decrease in introital tenderness and pain, and 6 of the 9 (66.7%) resumed sexual activity. Thus, 20 of the 29 women (69%) became sexually active. Following completion of treatment, 24 (88.9%) reported negligible or mild pain. Five of the 29 did not show any significant improvement, and none of them was able to resume sexual activity.

Bergeron and associates (2001) compared group CBT (12-week trial), surface EMG biofeedback (12-week trial), and vestibulotomy in the treatment of dyspareunia resulting from VVS. Subjects were 78 women randomly assigned to one of three treatment conditions and assessed at pre-treatment, post-treatment and 6-month follow-up via gynecological examinations, structured interviews and standard questionnaires pertaining to pain (Pain Rating Index and Sensory scale of the McGill Pain Questionnaire, vestibular pain index, pain during intercourse), sexual function (Sexual History Form, frequency of intercourse, Information
subscales of the Derogatis Sexual Functioning Inventory), and psychological adjustment (Brief Symptom Inventory). As compared with pre-treatment, study completers of all treatment groups reported statistically significant reductions on pain measures at post-treatment and 6-month follow-up, although the vestibulectomy group was significantly more successful than the other groups. However, the apparent superiority of vestibulectomy needs to be interpreted with caution since 7 women who had been assigned to this condition did not go ahead with the intervention. All 3 groups significantly improved on measures of psychological adjustment and sexual function from pre-treatment to 6-month follow-up. Intent-to-treat analysis supported the general pattern of results of analysis by treatment-received.

In a prospective, randomized study, Danielsson and co-workers (2006) assessed the effectiveness of EMG biofeedback and topical lidocaine treatment for women with vulvar vestibulitis (n = 46). Patients were randomized to receive either EMG biofeedback or topical lidocaine treatment for 4 months. Assessments with vulvar pressure pain thresholds and questionnaires regarding quality of life, psychosocial adjustments, and sexual functioning were made before treatment, after treatment, and at 6- and 12-month follow-ups. Non-parametric statistical methods were used to analyze differences in outcomes. Nine women dropped out during the treatment period. Both treatments showed significantly improved values for vestibular pressure pain thresholds, quality of life (QOL) measurements, and sexual functioning at the 12-month follow-up. No differences were found between the 2 treatment groups. No differences in outcome between the 2 treatments were observed but a larger sample may be needed to obtain significance. The treatments were well-tolerated but the compliance to the EMG biofeedback training program was low.

In a follow-up of their 2001 study, Bergeron and colleagues (2008) estimated if treatment gains would be maintained from the last assessment (a 6-month follow-up) to the 2.5-year follow-up. Although all three interventions yielded significant improvements at 6-month follow-up, vestibulectomy resulted in approximately twice the pain reduction as compared with the two other treatments. A second goal of the present study was to identify predictors of outcome. A total of 51 of the 78 women from the original study were re-assessed. They completed (i) a gynecological examination involving the cotton-swab test, (ii) a structured interview, and (iii) validated pain and sexual functioning measures. Results from the multi-variate analysis of variance conducted on the pain measures showed a significant time main effect (p < 0.05) and a significant treatment main effect (p < 0.01), indicating that subjects had less pain at the 2.5-year follow-up than at the previous 6-month follow-up. Results from the multi-variate analysis of variance conducted on sexual functioning measures showed that subjects remained unchanged between the 6-month and 2.5-year follow-up and that there were no group differences. Higher pre-treatment pain intensity predicted poorer outcomes at the 2.5-year follow-up for vestibulectomy (p < 0.01), biofeedback (p < 0.05), and CBT (p < 0.01). Erotophobia also predicted a poorer outcome for vestibulectomy (p < 0.001).

While there are reports that found biofeedback, with or without EMG, to be beneficial for patients with vulvodynia/vulvar vestibulitis, the number of patients in those studies only ranged from 29 to 78 -- relatively small patient populations.
Outcome measures in those studies included self-reported pain and frequency of sexual activity, as well as return to usual activity. Analysis of EMG findings were also furnished in some studies. However, since there are no known normative values for these parameters, these findings must be interpreted with caution. Moreover, no definite selection criteria have been established for the use of biofeedback in the treatment of patients with vulvodynia/vulvar vestibulitis.

Lavy and associates (2005) assessed the success of a simple modified vestibulectomy in treating vulvar vestibulitis. A total of 59 patients refractory to non-surgical treatment underwent modified vestibulectomy. Response was defined as return to normal coitus and was graded as complete, partial or non-responsive. The post-operative follow-up period was 6 months to 10 years. Thirty-nine (73.6 %) patients reported complete response, 7 (13.2 %) had partial response, and 7 (13.2 %) failed surgery. The authors concluded that surgery is an effective treatment for vulvar vestibulitis refractory to conservative treatment. Simple modified vestibulectomy is considerably less invasive, technically simpler and probably less time consuming. Post-operative results employing this surgical procedure are found to be in line with post-operative results reported by others who employ surgical methods that are more extensive.

Goldstein et al (2006) determined patient satisfaction with vestibulectomy for VVS and the rate of complications with this procedure. The primary outcome measurement of surgical success was overall patient satisfaction. Secondary outcome measurements included improvement in dyspareunia, changes in coital frequency, and occurrence of surgical complications. A total of 134 women underwent surgery in a 5-year period. A total of 106 women were contacted, and 104 participated in the study. Mean duration since surgery was 26 months. A total of 97 women (93 %) were satisfied or very satisfied with the outcome of their surgery. Only 3 patients (3 %) reported persistently worse symptoms after surgery and only 7 (7 %) reported permanent recurrence of any symptoms after surgery. Prior to surgery, 72 % of the women were completely aperiodic; however, after surgery, only 11 % were unable to have intercourse. The authors concluded that in this cohort of patients, there was a high degree of satisfaction with surgery for VVS. In addition, the risks of complications with this procedure were low, and most complications were transient and the risk of recurrence after surgery was also found to be low.

Traas et al (2006) studied the outcome and complications of surgical treatment for VVS and identified patient characteristics that may have influenced the outcome. Relevant patient characteristics were extracted retrospectively from the medical records of 155 women aged 40 years or younger who had received surgical treatment for VVS. To assess outcome and complications, 126 of these 155 women (81 %) participated in a telephone interview, conducted 1 to 4 years after surgery. After surgery, 93 % of the patients could have sexual intercourse compared with 78 % before surgery; this increase was statistically significant (Mantel-Haenszel odds ratio 3.43, 95 % confidence interval [CI]: 1.48 to 7.96). In 62 % of the women (95 % CI: 53 to 70 %), sexual intercourse was painless after surgery. Eighty-nine percent (95 % CI: 84 to 95 %) would recommend surgical treatment to other women experiencing VVS. There were no major complications. Decreased lubrication during sexual arousal was the most frequently reported adverse effect (24 %, 95 % CI: 16 to 32 %), followed by the development of a
Bartholin's cyst (6%, 95% CI: 2 to 10%). More of the women aged 30 years or younger reported that they could have sexual intercourse after surgery, and more of them would recommend surgical treatment to other patients than women aged 31 years or older. The authors concluded that surgical treatment for VVS achieved high success rates with an acceptable rate of complications. Age of 30 years or younger was associated with a better outcome.

In a prospective, randomized study, Bornstein and colleagues (1995) evaluated the effectiveness of vestibuloplasty in the treatment of severe vulvar vestibulitis (n = 21). Patients underwent either perineoplasty or vestibuloplasty. Differences in outcome between groups were analyzed using Fisher's exact test. Vestibuloplasty failed to relieve symptoms in 10 women, while perineoplasty resulted in complete resolution of symptoms in 9/11 women (p < 0.002). The authors concluded that the poor outcome of vestibuloplasty, if also reported by other centers, may render it an unacceptable therapy for vulvar vestibulitis. Vestibuloplasty aims to denervate sensitive vestibular tissue, and its failure may suggest that innervation disturbances are not the main cause of the syndrome.

Alo and colleagues (1999) reported that lumbar and sacral nerve root stimulation through the retrograde approach resulted in adequate paresthesia and effective pain relief as reflected by visual analog scale scores in 5 patients with chronic pain including 1 with vulvodynia. These investigators concluded that further clinical trials are needed to assess the safety and long-term success rates of lumbar/sacral nerve root stimulation in the management of patients with chronic pain.

In a case study, Ramsay et al (2009) reported the findings of sacral neuromodulation in the treatment of vulvar vestibulitis syndrome. Subject was a 42-year old woman who exhibited symptoms consistent with chronic vulvar vestibular syndrome that was refractory to multiple attempted therapies. She underwent a standard 2-phase surgical implantation with good result at 2 years post-implantation. The authors concluded that sacral neuromodulation was shown to be a valid treatment option for this patient and resulted in excellent patient satisfaction at 2-year follow-up. They stated that although the exact mechanism of action is unknown, sacral neuromodulation may be a viable option for the management of chronic pain syndromes of the vulva and vagina. While the results of this single case study are promising, larger randomized studies are needed to ascertain the role of this therapy in treating vulvar vestibulitis syndrome.

In a pilot study (n = 14), Danielsson and associates (2001) examined the effectiveness of acupuncture in the treatment of vulvar vestibulitis. Patients with vulvar vestibulitis according to Friedrich's criteria were enrolled in the study and 13 fulfilled the acupuncture treatment a total of 10 times. Quality of life assessments were made before treatment and then at 1 week and at 3 months after treatment. Acupuncture was well-tolerated and the QOL measurements were all significantly higher after both the last acupuncture and 3 months later, compared to pre-treatment. The authors concluded that these findings appeared promising, but a larger, randomized, controlled study should be carried out before the treatment can be recommended for use in clinical practice.

Whiteside and associates (2003) reported their findings of a 21-year old woman who had a long history of burning vulvar pain exacerbated by exercise and sexual
intercourse. Her symptoms began after termination of pregnancy and were not improved by diet changes or medical therapy. A partial vulvar vestibulectomy with Bartholin gland excision was performed, without an improvement. After referral to a pain management specialist, the patient had temporary relief of symptoms following bilateral hypogastric plexus blocks. With these favorable but temporary results, a permanent spinal cord stimulator was implanted, with sustained symptom relief. The authors concluded that spinal cord stimulation may offer a new treatment for women with intractable neuropathic vulvar pain.

It has been suggested that vaginal acupuncture (VA), also known as Hippocratic pelvic massage, can help some gynecological and sexological problems including vulvodynia. This procedure corresponds to the explorative phase of the standard pelvic examination, supplemented with the patient's report on the feelings it provokes and the processing and integration of these feelings. In a pilot study, Ventegodt and colleagues (2006) reported their findings of 20 patients with a long history of sexual problems (mean of 8.92 years) who received VA with a quantitative and qualitative evaluation: 56% experienced help and none reported setbacks, 89% rated the treatment to be of high quality, and 89% rated it as valuable. After the treatment, most reported their problems to be less serious and their general QOL improved. Only 17% reported minor or temporary side effects. Vaginal acupuncture was found statistically and clinically significant (p < 0.05, improvement more than 0.5 step on a 5-point Likert scale) to help patients with chronic genital pains, pain or discomfort during sexual intercourse, lack of desire or orgasm, and subjective sexual insufficiency, and all patients taken as one group (about 1 step up a 5-point Likert scale). Self-evaluated physical and mental health was significantly improved for the total group; the relationship with partner, the subjective sexual ability, and the QOL that were measured with QOL1 and QOL5 questionnaires were all significantly improved. The authors concluded that acupuncture through the vagina/pelvic massage must be done according to the highest ethical standard with great care, after obtaining consent and the necessary trust of the patient within the framework of the local laws.

Yoon and associates (2007) examined the effectiveness of botulinum toxin A for the management of vulvodynia. A total of 7 women with pain on genitalia that could not be controlled with conventional pain management were enrolled in this study. Twenty to 40 units of botulinum toxin A were used in each injection. Injection sites were the vestibule, levator ani muscle or the perineal body. Repeat injections were administered every 2 weeks if the patient's symptoms had not fully subsided. In all patients, pain disappeared with botulinum toxin A injections. Five patients needed to be injected twice; the other 2 patients needed only one injection. There were no observable complications related to botulinum toxin A injections, such as pain, hemorrhage, infection, muscle paralysis or other complications. The subjective pain score improved from 8.3 to 1.4; and no one has experienced a recurrence (the follow-up period was 4 to 24 months, with a mean follow-up of 11.6 months). The authors suggested that botulinum toxin therapy might be safe and useful in managing vulvodynia of muscular or neuro-inflammatory origins even though further investigation and well-controlled studies are needed to confirm these findings.

In a preliminary study, Pukall et al (2007) examined the effectiveness of hypnosis on pain and psychosexual function in VVS. A total of 8 patients completed a
hypnosis screening assessment, an interview, pain and psychosexual questionnaires, a gynecological examination, vestibular pain threshold measurement, a psychosexual assessment, and 6 hypnotherapy sessions. The physical examinations, interview, and questionnaires were repeated at 1 and 6 months post-treatment. Main outcome measures included pain ratings during the gynecological examination, vestibular pain thresholds, scores on the McGill Pain Questionnaire and Pain Catastrophizing Scale, and responses to questions on intercourse-related and non-intercourse-related pain. Measures of psychosexual function included the Female Sexual Function Index, State-Trait Anxiety Scale, Beck Depression Inventory-II, and the Brief Symptom Inventory. Results indicated significant decreases in gynecological examination pain and in several measures assessing intercourse pain, and non-significant increases in threshold. Some indices of non-coital vulvar pain decreased. Overall sexual function, particularly sexual satisfaction, increased at post-treatment. There were no differences on any psychological measure. Participants reported satisfaction with the treatment and rated their VVS pain reduction as average. The authors concluded that hypnotherapy appears to be a promising treatment for reducing intercourse pain and some aspects of non-coital vulvar pain, and for restoring sexual function in women with VVS. They noted that these results suggested that a large controlled trial should be considered.

Zawislak and co-workers (2007) evaluated the applicability of photodynamic therapy (PDT) in the treatment of vulvodynia. A total of 11 patients underwent PDT using a bio-adhesive patch to deliver 5-aminolevulinic acid (ALA) over 4 hours to vulvar regions displaying the characteristics of vulvodynia. A non-laser light source delivered 100 J cm(-2) to the target area using red light of 630 nm. Fluorescence of protoporphyrin IX was observed under ultraviolet light illumination, with no significant difference found between that produced after the first and second applications of the patch. There was a significant reduction (p = 0.0077) in overall symptoms after completion of treatment. No significant alleviation (p = 0.1088) in pain during intercourse was observed following treatment. A total of 8 patients experienced a symptomatic response, while 3 exhibited no improvements in symptoms. No adverse reactions or worsening of reported symptoms was reported. The authors concluded that these findings suggested that PDT is of value in the management of vulvodynia. They stated that further studies involving larger numbers of patients are needed to confirm the effectiveness of PDT in the management of vulvodynia.

Munday et al (2007) assessed the response of a group of women with vulvodynia who were participating in an integrated, multi-disciplinary management program comprising medical evaluation and treatment, psychotherapy, physiotherapy and dietary advice. Twenty-seven of 29 women reported a significant benefit, and 9 who had completed the program were pain-free. All women appreciated the integrated approach, and even those who were not completely pain-free found that they were able to manage their condition satisfactorily. The authors concluded that further evaluation of this program is warranted to assess whether it would be helpful for other women with this problem.

Beco et al (2004) noted that perineodynia (e.g., vulvodynia, perineal pain, proctalgia), anal and urinary incontinence are the main symptoms of the pudendal canal syndrome (PCS) or entrapment of the pudendal nerve. In a case-series
study, these investigators evaluated the effect of bilateral pudendal nerve
decompression (PND) on the symptoms of the 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 [EMG] and pudendal nerve
terminal motor latencies [PNTML]). The second aim was to study the clinical value
of the afore-mentioned clinical signs in the diagnosis of PCS. In this retrospective
analysis, the studied sample comprised 74 female patients who underwent a
bilateral PND between 1995 and 2002. To accomplish the first aim, the patients
sample was compared before and at least 1 year after surgery by means of
descriptive statistics and hypothesis testing. The second aim was achieved by
means of a statistical comparison between the patient's group before the operation
and a control group of 82 women without any of the following signs (i.e., prolapse,
anal incontinence, perineodynia, dyschesia and history of pelvi-perineal surgery).
When bilateral PND was the only procedure done to treat the symptoms, the cure
rates of perineodynia, anal incontinence and urinary incontinence were 8/14, 4/5
and 3/5, respectively. The frequency of the 3 clinical signs was significantly
reduced. There was a significant reduction of anal and perineal PNTML and a
significant increase of anal richness on EMG. The authors concluded that the
findings of this study suggested that bilateral PND can treat perineodynia, anal
and urinary incontinence. The 3 clinical signs of PCS seem to be efficient to
suspect this diagnosis. They stated that there is a need for further studies to
confirm these preliminary results.

In a prospective study, Rapkin et al (2008) evaluated a novel treatment approach,
multi-level local anesthetic nerve blockade, for the treatment of VVS (n = 27). The
protocol included 5 treatment sessions with caudal epidural, pudendal nerve block,
and vestibular infiltration of local anesthetic agents. There were significant
improvements in vestibular pain as determined by the vulvalgesiometer, McGill
pain questionnaire, self-report, and the Female Sexual Functioning Inventory. The
authors concluded that serial multi-level nerve blocks administered for the
treatment of VVS is a conceptually neurophysiologically based modality that may
be effective and merits a placebo-controlled study.

The American Society for Colposcopy and Cervical Pathology (ASCCP)'s guideline
on vulvodynia (Haefner et al, 2005) stated that many treatments have been
employed for patients with vulvodynia, including vulvar care measures; topical,
oral, and injectable medications; biofeedback; PT; low-oxalate diet and calcium
citrate supplementation; as well as surgery. Surgical intervention is the last resort
and is usually grouped into 3 categories: (i) local excision, (ii) total vestibulectomy,
and (iii) perineoplasty. Local excision entails precise localization of small painful
areas followed by shallow excision of the tissue. Total vestibulectomy is an out-
patient procedure most often performed under spinal or general anesthesia.
Patients undergo testing with a cotton swab before anesthesia while in the
operating room to outline the areas of pain. Often, pain may be present throughout
the vestibule. The incision may need to approach the peri-urethral area and
extend from the openings of Skene's ducts to the perineum. Perineoplasty entails
combination of vestibulectomy and removal of tissue on the perineum, usually
terminating just above the anal orifice.

The 2005 ASCCP guideline also stated that vestibuloplasty (an operation aimed at
denervating the vestibule without excision of the painful tissue) has been shown to
be ineffective. Moreover, perineal pain caused by pudendal nerve entrapment is a rare entity. When patients have failed guided nerve blocks with corticosteroids, TCAs, anti-convulsants, and PT, surgical decompression of pudendal nerve is an option. Newer therapies for patients with vulvodynia include acupuncture, hypnotherapy, nitroglycerin, and botulinum toxin. However, it should be noted that the type of evidence supporting the recommendations was not specifically stated; the guideline was based largely on expert opinion.

The American College of Obstetricians and Gynecologists (ACOG) Committee Opinion on vulvodynia (2006) was adapted from the 2005 ASCCP guideline. It stated that most of the available evidence for the treatment of vulvodynia is based on clinical experience, descriptive studies, or reports of expert committees. There are few randomized controlled trials (RCTs) of vulvodynia treatments. Vulvodynia is a complex disorder that is difficult to treat, and rapid resolution is unusual even with proper treatment. Decrease in pain may take weeks to months and may not be complete. No single treatment is successful in all women.

In a "white paper" on the definition, diagnosis, and management of vulvodynia, Bachmann et al (2006) stated that all currently used interventions (e.g., systemically administered drugs, topical applications of corticosteroids, estrogen, anti-inflammatory agents, and anesthetics, dietary approaches, PT, pelvic floor manipulation, EMG biofeedback, as well as electroanalgesia or antalgic block of the ganglion impar) have limited data objectively measuring safety and effectiveness. There are no standardized, evidence-based treatment guidelines or algorithms since clinical trials have not been performed to allow evidence-based guidelines. Excisional vestibular surgery is an approach advocated in some centers for localized vulvodynia when other treatments have failed. The panel concurred on the need for evidence-based, "stepped care" guidelines for clinical management of vulvodynia. This "white paper" also recommended more investigation on alternative therapies (e.g., acupuncture, aromatherapy, hypnosis, as well as dietary restrictions). Therapeutic interventions should be systematically evaluated in prospective RCTs, especially multi-center trials, when possible.

Reed (2006) stated that several approaches have been employed for the treatment of vulvodynia although the evidence for many of these treatments is incomplete. The author noted that local therapy such as biofeedback has been used to help patients regain control of the pelvic floor musculature; however, the bvalue of most local treatments has not been determined. Furthermore, the author noted that the evidence rating on the use of biofeedback for vulvodynia is "B" (inconsistent or limited-quality patient-oriented evidence). Surgery is reserved for individuals with severe symptoms. The author also stated that carbon dioxide laser surgery was used for the vulva and vestibule for several years, but this approach is no longer recommended because of the scarring and worsening of symptoms that can follow. The use of other dye laser protocols remains controversial.

Landry et al (2008) performed a critical review of published studies concerning the treatment of provoked vestibulodynia. All studies published in English that dealt specifically with the treatment of provoked vestibulodynia were included in the review regardless of their methodological quality. A total of 38 treatment studies were examined in the present paper. Since 1996, surgical treatment has received
somewhat less empirical attention. Nevertheless, it still boasts the best success rates that ranged from 61% to 94%. More studies have focused on medical treatments, yielding success rates that varied between 13% and 67%. Behavioral treatments have been the least studied, although 35% to 83% of patients benefit from them. Despite these interesting results, only 5 of the 38 treatment studies reviewed are RCTs. Furthermore, the majority of studies have several methodological weaknesses, such as the absence of (i) control or placebo group, (ii) double-blind evaluation, (iii) pre-treatment pain evaluation, and (iv) validated measures of pain and sexual functioning. On the basis of the results of the reviewed prospective studies and RCTs, vestibulectomy is the most effective treatment to date. Although some medical treatments appear ineffective, others appear promising and should be investigated further, as is the case with behavioral treatments.

In a review on vulvodynia, Stewart (2008) noted that PT is most useful for patients with vulvodynia if vaginismus, back pain, or muscle spasm are present. High muscle tone or spasm and instability within the pelvic floor musculature can be identified and relieved with specific exercises. The author also noted that interferon is considered about as effective as placebo and is not in standard use. Furthermore, laser in any wave length is not of value in the treatment of vulvodynia.

Cecil and colleagues (2008) stated that existing therapies for vulvodynia are inadequate. Because vulvodynia has a pathophysiology similar to chronic pain, central nervous system dysfunction may underlie this painful disorder, and non-invasive methods of neuromodulation may prove highly effective. These investigators reported a case of severe, medically refractory vulvodynia that responded remarkably to treatment with transcranial direct current stimulation. The findings of this case study need to be validated by well-designed studies.

In a 12-week randomized, double-blinded, placebo-controlled trial, Foster et al (2010) examined the effectiveness of topical lidocaine monotherapy, oral desipramine monotherapy, and lidocaine-desipramine combined therapy for the treatment of vulvodynia. A total of 133 vulvodynia-afflicted women were assigned to 4 treatment arms: (i) placebo tablets-placebo cream, (ii) desipramine tablets-placebo cream, (iii) placebo tablets-lidocaine cream, and (iv) desipramine tablets-lidocaine cream. The tampon test was selected as primary end point using a modified intention-to-treat analysis. Twelve secondary end points were also examined. At completion of the 12-week randomized phase, women were examined "open label" through 52 weeks post-randomization. All treatment arms reported substantial tampon-test pain reduction: 33% reduction placebo cream-placebo tablet, 20% reduction lidocaine cream-placebo tablet, 24% reduction placebo cream-desipramine tablet, and 36% reduction lidocaine cream-desipramine tablet. Compared with placebo, these researchers found no significant difference in tampon-test pain reduction with desipramine (t = 0.90; p = 0.37) or lidocaine (t = 1.27; p = 0.21). Of the remaining 12 outcome measures, only the Index of Sexual Satisfaction, improved with desipramine compared with placebo (t = -2.81; p = 0.006). During the open-label phase, women undergoing vestibulectomy surgery reported significantly improved pain as measured by cotton swab test and the McGill Pain Scale compared with nonsurgical alternatives. The authors concluded that oral desipramine and topical lidocaine,
as monotherapy or in combination, failed to reduce vulvodynia pain more than placebo. Placebo or placebo-independent effects are behind the substantial pain improvement seen in all treatment allocations.

Bornstein et al (2010) performed a double-blind placebo-controlled study to investigate the effectiveness of 2 concentrations of topical nifedipine cream in the treatment of vulvodynia. A total of 30 participants were alternately assigned to 3 topical treatment groups: (i) 0.2 % nifedipine, (ii) 0.4 % nifedipine, and (iii) placebo. All administered the cream to the vestibule 4 times daily for 6 weeks. For all 3 treatment groups, mean pain intensity on vestibular touch, assessed by the Q-tipped cotton test, pain from speculum insertion, and reports of pain during sexual intercourse was reduced at post-treatment compared with pre-treatment. These improvements remained at 3 months’ follow-up. The effectiveness of nifedipine in treating vulvodynia did not exceed that of placebo. The authors concluded that topical application of nifedipine and a placebo reduced pain in women with vulvodynia. They stated that these findings highlight the need for controlled trials of treatments for vulvodynia and raises doubts about studies conducted without comparison to placebo.

In a prospective, non-controlled, pilot study, McDonald and Rapkin (2012) examined the effectiveness of a novel treatment using caudal epidural, pudendal nerve block, and vulvar infiltration of local anesthetic agents for the treatment of generalized vulvodynia. The main outcome measure was vulvar pain as assessed by the McGill Pain Questionnaire (MPQ). The secondary outcome measures were depressed mood evaluated with the Beck Depression Inventory (BDI) and sexual functioning assessed by the Female Sexual Functioning Inventory (FSFI). A total of 32 women with vulvodynia met inclusion criteria and 26 women completed the study. The protocol included 5 treatment sessions with multi-level local anesthetic nerve blockade and a follow-up contact or visit 2 to 3 months later. There were significant improvements in vulvar pain as determined by both the sensory and affective components of the MPQ and in depression as assessed by the BDI. However, there were no changes in sexual functioning on the FSFI. The authors concluded that serial multi-level nerve block administered for the treatment of vulvodynia is a neurophysiologically based modality that may be effective, and merits a placebo-controlled study.

Leo and Dewani (2013) noted that anti-depressants have often been recommended as a potential treatment for the management of vulvodynia. However, review of the evidence supporting this recommendation has not been systematically assessed. These researchers evaluated the effectiveness of anti-depressant pharmacotherapy in the treatment of vulvodynia. An assessment of the methodological quality of published reports addressing the utility of anti-depressants in the treatment of vulvodynia was undertaken. Several secondary outcomes generated in the existing literature were also examined. A comprehensive search of the available literature was conducted. The search yielded 13 published reports, i.e., 2 RCT, 1 quasi-experimental trial, 7 non-experimental studies, and 3 case reports. A number of methodological shortcomings were identified in several of the reports with respect to study design including lack of clear inclusion/exclusion criteria, small sample sizes, lack of comparison groups, insufficient blinding, among others. The vast majority of studies utilized tricyclic antidepressants (TCAs). Evidence supporting the benefits
of TCAs studied to date was limited, i.e., based largely upon descriptive reports but unsubstantiated by RCTs. There were no systematic investigations into the comparative effectiveness of different anti-depressant classes in the treatment of vulvodynia. The authors concluded that there is insufficient evidence to support the recommendation of anti-depressant pharmacotherapy in the treatment of vulvodynia. Although some vulvodynia-afflicted patients derive symptom relief from anti-depressants, additional research is needed to identify those characteristics that would predict those patients for whom anti-depressants are more likely to be effective.

Spoelstra et al (2013) stated that anti-convulsant therapy has occasionally been recommended to treat vulvodynia. However, convincing evidence to support this therapeutic option is lacking. These investigators reviewed studies published on the effectiveness of anti-convulsants for the treatment of vulvodynia. Evaluation of the methodological quality of relevant publications was the main outcome measure. Medline, PubMed and Cochrane were used to identify studies published in English between January 1999 and February 2013. Searches were performed between December 2012 and February 2013. Articles were appraised with the Oxford Centre for Evidence-Based Medicine - Levels of Evidence. A total of 8 relevant studies were identified: 2 case reports, 3 retrospective studies, 2 non-randomized prospective studies, and 1 open-label pilot trial study. Gabapentin formed the main focus (87.5%) to reduce vulvar pain; success rates ranged from 50 to 82%. Lamotrigine was used in 1 study (12.5%) to relieve symptoms; satisfaction was reported in 82%. These results seem promising, but the majority of studies have several methodological weaknesses regarding sample size and design. The authors concluded that insufficient evidence was available to recommend anti-convulsants for the treatment of vulvodynia. They stated that further studies are necessary with double-blind, randomized-controlled designs to investigate the effectiveness of anti-convulsant therapy for vulvodynia.

Leo (2013) evaluated the effectiveness of anti-convulsant pharmacotherapy in the treatment of vulvodynia. An assessment of the methodological quality of published reports addressing the utility of anti-convulsants in the treatment of vulvodynia was undertaken. The search yielded 9 published reports, i.e., 1 open-label trial, 6 non-experimental studies, and 2 case reports. A number of methodological shortcomings were identified in several of the reports with respect to study design, including small sample sizes, lack of placebo or other comparison groups, inadequate outcome measures, among others. The vast majority of studies employed gabapentin. Evidence supporting the benefit of anti-convulsants studied to date was limited, i.e., based predominantly upon descriptive/observational reports. There were no systematic investigations into the comparative effectiveness of different anti-convulsant agents in the treatment of vulvodynia. The authors concluded that although some vulvodynia-afflicted patients derive symptom relief from anti-convulsants, there is, as yet, insufficient evidence to support the recommendation of anti-convulsant pharmacotherapy in the treatment of vulvodynia. They stated that additional investigations, employing RCTs, are warranted.

Kestranek et al (2013) described radiofrequency therapy, a new and hopeful possibility in the treatment of refractory severe vulvodynia. These investigators reported on the successful use of the pulsed radiofrequency treatment in a patient.
with intractable chronic vulvodynia. The authors stated that to their knowledge, this was the first report of a successful use of pulsed radiofrequency in the treatment of chronic vulvodynia. They concluded that if the effectiveness of pulsed radiofrequency is confirmed by more studies, it would be a welcome addition to the treatment modalities used to treat this sometimes truly intractable condition.

Brown and colleagues (2013) noted that few RCTs have been conducted to establish evidence-based management protocols for provoked vestibulodynia (PVD), a chronic vulvar pain condition affecting approximately 14 million women in the U.S. These researchers described the rationale and design of a National Institutes of Health-funded multi-center clinical trial utilizing an extended release formulation of gabapentin (G-ER), an intervention that preliminary data suggested may be effective for this condition. The objectives of this trial are: (i) to determine if pain from tampon insertion (primary outcome measure) is lower in PVD patients when treated with G-ER compared to when treated with placebo, and (ii) to determine if G-ER reduces vulvar mechanical hyperalgesia, vaginal muscle pain to palpation, the number and intensity of somatic tender-points, spontaneous and provoked pain to intra-dermal capsaicin with an accompanying increase in cardiac beat-to-beat variability and to identify mechanistically-based PVD subtypes. Additional outcomes include subject reported intercourse pain and summative 24-hour pain. This 16-week, randomized, double-blind, placebo-controlled, cross-over study will enroll 120 women 18 years and older who report tenderness localized to the vulvar vestibule, pain with tampon insertion, and, when sexually active, insertional dyspareunia. Electronically entered daily diaries will be used to determine if pain is lower in PVD subjects when treated with G-ER (up to 3,000 mg/day) compared to when treated with placebo. Psychophysiological measures will be obtained at baseline and after 2 weeks at the maximum tolerated dose.

A Committee Opinion from the American College of Obstetricians and Gynecologists on vulvodynia (ACOG, 2006) stated that commonly prescribed topical medications include a variety of local anesthetics (which can be applied immediately before intercourse or in extended use), estrogen cream, and tricyclic antidepressants compounded into topical form. Guidelines on vulvodynia from the British Society for the Study of Vulval Disease (Nunns, et al., 2010) state that a trial of a local anaesthetic agent may be considered in all vulvodynia subsets (Grade of recommendation C; evidence level IV).

Weinschenk et al (2013) reported on a case of a 25-year old woman with generalized, unprovoked vulvodynia for 12 years who was treated repeatedly with procaine 1% for 14 sessions after she had previously had numerous unsatisfying multi-disciplinary treatments. These researchers observed a decrease in pain scores on the visual analog scale (VAS) from initially 8 to 9 to presently 0 to 2. Injection sites were: Head's zones and trigger points of the lower abdomen, regional hypo-gastric ganglia, bilateral maxillary sinus, and scars of the lower jaw. No major adverse events were observed. Injections to remote sites improved symptoms more strongly than local or regional therapy. After a 3-year follow-up the patient was free of symptoms. The authors concluded that therapy with local anesthetics can be a useful additional therapy in complicated cases of vulvodynia. Moreover, they stated that further studies on the underlying mechanism of injections into remote foci and the effectiveness of tumescent local anesthesia in chronic pain syndromes should be performed.
De Andres et al (2013) reported on the case of a 35-year old woman with 3 years of dysesthetic vulvodynia who had tried conventional and interventional medical treatment with inadequate relief. She was offered peripheral subcutaneous vulvar field stimulation and underwent implantation of 2 vulvar subcutaneous electrodes. At 15 days after treatment and during 1-year follow-up, the patient scored 1 out of 15 on Friedrich scale, 1 out of 10 on the VAS, and 1 out of 10 on the tampon test. The patient no longer required oral medication. The authors concluded that stimulation with subcutaneous electrodes provided relief from vulvodynia to a patient in whom all previous therapeutic approaches had failed. The findings of this single-case study need to be validated by well-designed studies.

Corbett and colleagues (2014) identified trends in compounding pharmacies with a focus on women's health and, more specifically, the types and combinations of medications used in the treatment of vulvodynia. This survey was conducted with 653 non-chain pharmacies that compound medications. Each pharmacy was asked to complete a 19-item online survey assessing general practice and common compounding indications, focusing on women's health. Of the 653 pharmacies contacted, 200 (31 %) responded to the survey. Women's health issues ranked 3rd (19 %) among the common indications for compounding, preceded by otolaryngology (30 %) and dermatology (28 %). Of the medications compounded for women's health, the most common indication was bioidentical hormone therapy (73 %) followed closely by vaginal dryness (70 %) and low libido (65 %). Vulvodynia, or vulvar pain, was the 4th most common indication for compounding medication for women's health issues (29 %). Vulvovaginal infections were reported as an indication for compounding medications by 16 % of respondents. The authors concluded that vulvo-vaginal symptoms are a common indication for compounding medications in women's health. Moreover, they stated that further research in understanding the rationale for using compounded medications, even when standard treatments are available for some of these symptoms (e.g., vaginal dryness, vulvo-vaginal infections), is warranted.

Keppel Hesselink et al (2014) stated that the prevalence of idiopathic vulvodynia and proctodynia is high. Pain management with anti-depressants and anti-epileptics may induce undesirable side effects. Therefore, topical baclofen cream and palmitoylthanolamide might be new therapeutic options. These researchers reported on the case of a 33-year old woman with intractable chronic vulvar and anal pain who had to abstain from sexual intercourse and could neither cycle nor sit for more than 5 mins. The patient did not respond to standard treatments. These investigators prescribed a combination of topical baclofen 5 % and palmitoylthanolamide (a naturally occurring fatty acid amide with anti-inflammatory activity) 400 mg, 3 times daily. After 3 months her symptoms decreased more than 50 % and sexual intercourse was possible again without pain. The authors concluded that topical baclofen and palmitoylthanolamide can be a viable treatment option in chronic vulvodynia and proctodynia. The findings of this single-case study need to be validated by well-designed studies.

In a pilot study, Corsini-Munt et al (2014) tested the feasibility and potential effectiveness of a novel cognitive-behavioral couple therapy (CBCT) for couples coping with PVD. Couples (women and their partners) in which the woman was diagnosed with PVD (n = 9) took part in a 12-session manualized CBCT
intervention and completed outcome measures pre- and post-treatment. The primary outcome measure was women's pain intensity during intercourse as measured on a numerical rating scale. Secondary outcomes included sexual functioning and satisfaction for both partners. Exploratory outcomes included pain-related cognitions; psychological outcomes; and treatment satisfaction, feasibility, and reliability. One couple separated before the end of therapy. Paired t-test comparisons involving the remaining 8 couples demonstrated significant improvements in women's pain and sexuality outcomes for both women and partners. Exploratory analyses indicated improvements in pain-related cognitions, as well as anxiety and depression symptoms, for both members of the couple. Therapists’ reported high treatment reliability and participating couples’ high participation rates and reported treatment satisfaction indicate adequate feasibility. The authors concluded that treatment outcomes, along with treatment satisfaction ratings, confirmed the preliminary success of CBCT in reducing pain and psychosexual burden for women with PVD and their partners. Moreover, they stated that further large-scale RCTs are needed to examine the effectiveness of CBCT compared with and in conjunction with first-line biomedical interventions for PVD.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes covered if selection criteria are met:

56620 -
56640

56810

97010 -
97032, 97034
- 97039

97110 -
97139

CPT codes not covered for indications listed in the CPB:

56800

63650

63655

63685

64550

64561

64581

64614
Other CPT codes related to the CPB:

57284

57285

HCPCS codes not covered for indications listed in the CPB:

J0585  Botulinum toxin type A, per unit

J0587  Botulinum toxin type B, per 100 units

S8948  Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes

ICD-9 codes covered if selection criteria are met:

625.70 - Vulvodynia [vulvodynia and vulvar vestibulitis]

625.79

The above policy is based on the following references:


http://qawww.aetna.com/cpb/medical/data/700_799/0759_draft.html

11/26/2014