Clinical Policy Bulletin:
Levator Syndrome Treatments

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Policy

Aetna considers high-voltage pulsed electrogalvanic stimulation medically necessary for members with refractory levator syndrome (also known as proctalgia fugax, chronic anal pain syndrome) when all the following criteria are met:

A neurological cause for the pain can not be detected; and
Member has failed prior conservative treatments, namely, high-fiber diet, withdrawal of drugs that cause constipation (e.g., calcium channel blockers, narcotics) or diarrhea (e.g., antibiotics, quinidine, theophylline), perineal strengthening exercises, rectal massage, warm baths, and drug therapy (e.g., muscle relaxants, non-narcotic analgesics, and sedatives); and
No underlying disease has been revealed by anorectal examination or by manometry, radiology, or endoscopy.

Aetna considers high-voltage pulsed electrogalvanic stimulation for levator syndrome experimental and investigational when criteria are not met.

Aetna considers biofeedback medically necessary for members with refractory levator syndrome when criteria listed above are met. (See CPB 0132 - Biofeedback).

Aetna considers botulinum toxin injections experimental and investigational for the treatment of levator syndrome because their effectiveness for this indication has not been established. (See CPB 0113 - Botulinum Toxin).

Aetna considers sacral nerve stimulation experimental and investigational for the treatment of levator syndrome because the effectiveness of this approach has not been established.

Note: More than 3 60-min sessions, administered over a 10-day period, are not considered medically necessary. Electrogalvanic stimulators for home use are considered experimental and investigational because they have not been proven to be safe and effective for home use.

http://qawww.aetna.com/cpb/medical/data/600_699/0679_draft.html
**Background**

Levator syndrome (LS), also known as proctalgia fugax and chronic anal pain syndrome, is a benign disorder characterized by brief, episodic attacks of rectal discomfort and pain of varying severity. Although the term levator syndrome suggests that spasm of the levator ani muscles is the cause of symptoms, it is still unclear that this mechanism is responsible for all cases of functional rectal discomfort/pain. Attacks often occur suddenly at night, waking patients from sleep. In some cases, attacks may occur when the patient is straining at stool or after a bowel movement. The pain usually lasts for seconds to minutes, and then disappears completely. Most patients have less than 6 episodes a year, however, some patients experience attacks very frequently. The condition generally does not appear until after puberty and the frequency and severity of attacks decrease after age 60. The site of pain is located in the upper anal canal, just above the anal sphincter. Precipitating factors for this disorder include anxiety, stress, heat, cold, or fatigue (Thompson and Heaton, 1980).

Treatments of patients with LS include high-fiber diet, withdrawal of drugs which have gut effects (e.g., drugs that provoke or worsen constipation including narcotics and calcium channel blockers; drugs that provoke or worsen diarrhea including quinidine, theophylline, and antibiotics), warm baths, rectal massage, perineal strengthening exercises, anti-cholinergic agents, non-narcotic analgesics, sedatives or muscle relaxants. High-voltage pulsed galvanic stimulation (HVPGS) has also been used in the treatment of this condition, and is not associated with any adverse side effects. It should be noted that HVPGS is generally not employed to treat patients while they are experiencing symptoms since the attacks usually last only for seconds to minutes. Instead, this technology is often used as a prophylactic means to reduce the incidence of attacks. The patient is usually placed in the left lateral decubitus position and a sterile probe is inserted into the anus. The negative electrode is used and the stimulator is set with a pulse frequency of 80 to 120 cycles per second. The voltage (intensity) is started at 0, progressively raised to a threshold of patient discomfort, and then is decreased to a level that the patient finds comfortable. As the patient's tolerance increases, the voltage can be gradually increased to 250 to 350 Volts. Each treatment session usually lasts between 15 to 60 mins (Oliver et al, 1985; Morris and Newton, 1987). Several studies have reported short-term success rates that ranged from 65 to 91 % (Sohn et al, 1982; Nicosia and Abcarian, 1985; Oliver et al, 1985; Morris and Newton, 1987; Billingham et al, 1987).

Sohn et al (1982) reported that HVPGS is effective in treating patients with LS. Eighty patients participated in the study. Treatment duration was 1 hour per day, 3 times over a period of 3 to 10 days. Of the 72 patients evaluated, 90 % had excellent (total relief of pain and no recurrence of levator spasm during the course of follow up) or good (with complete resolution of pain but with recurrence of levator spasm at a markedly reduced frequency during the course of follow-up) results. Nicosia and Abcarian (1985) treated 45 patients with LS using HVPGS. Treatment time was 15 to 30 mins administered every other day for an average of 5 treatments. Excellent (complete pain relief) or good (relief was followed by
recurrence of pain that responded completely to additional treatment) results were observed in 91% of patients.

Oliver et al (1985) also employed HVPGS to treat 102 patients with LS. Patients had tried and failed conservative treatments before being included in this study. All treatments were 60 mins in duration, and a total of 3 treatments were provided within a 10-day period. Follow-ups consisted of 1 post-treatment office visit to the attending surgeon or by telephone interviews if the patient failed to return for follow-up examination. Of the 90 patients with correct diagnoses, 77% were relieved or improved after treatment. Morris and Newton (1987) reported their findings of 28 patients with LS treated with HVPGS. The number of treatments ranged from 3 to 10 with each session lasting for 60 mins. Overall, 75% patients reported complete or partial relief of pain/symptoms following HVPGS treatment.

In the study by Billingham et al (1987) 20 patients received an average of 5.6 treatment sessions of HVPGS treatment. Immediately after the first course of treatment, 65% of patients achieved excellent or good results. Several months after completion of therapy, results were classified as excellent in 4 (20%) patients, good in 4 (20%), fair in 6 (30%), and poor in 6 (30%). The authors concluded that although the long-term results of HVPGS are not as successful as the short-term results, this modality is still a valuable adjunct in the management of patients with LS.

In a randomized, placebo-controlled, cross-over study, Rao et al (2009) examined the safety and effectiveness of botulinum toxin in patients with LS. A total of 12 patients with LS (greater than or equal to 1 year) received anal intra-sphincteric injections of 100 units of botulinum toxin A and placebo at 90-day intervals using electromyographical guidance. Daily frequency, severity, duration and intensity of pain (by means of visual analog scale [VAS]) were recorded. Anorectal manometry, balloon expulsion and pudendal nerve latency tests were performed to examine the physiological changes and adverse effects. Seven patients (male/female = 4/3) completed the study and 3 had incomplete data, but all 10 underwent in an intention-to-treat analysis; 2 others dropped out. After administration of botulinum toxin, the mean frequency, intensity and duration of pain were unchanged (p = 0.31) compared with baseline. The 90-day mean VAS pain score was 6.79 +/- 0.27 versus baseline score of 7.08 +/- 0.29 (p = 0.25). Anal sphincter pressures, rectal sensory thresholds, pudendal nerve latency and balloon expulsion times were unchanged after drug or placebo administration. The authors concluded that injection of botulinum toxin into anal sphincter is safe, but it does not improve anorectal pain in LS.

Dudding and colleagues (2013) state that a small number of published case reports suggested that sacral nerve stimulation (SNS) could treat chronic idiopathic anal pain. In a pilot study, these researchers examined the effectiveness of SNS for the treatment of chronic anal pain. A total of 10 patients with chronic idiopathic anal pain were recruited. All had failed to respond to conservative treatments. Clinical and psychological evaluation was performed in all patients prior to SNS. Temporary stimulation of the S3 foramina was performed for 3 weeks and outcome assessed by comparison of a pain score diary and VAS obtained during stimulation and at baseline. Primary outcome was defined as a greater than 50% reduction in pain score. Of the 10 patients recruited, 5 were
found to have clinical depression; 4 patients withdrew from the study prior to testing and 6 underwent peripheral nerve evaluation (PNE). Three patients had greater than 50 % reduction in pain score and progressed to permanent SNS. Of these, only 1 had good pain control at latest follow-up of 5 years; the remaining 2 patients obtained no benefit and had their devices removed or de-activated. These 2 patients both had depression that was also not improved by SNS. The authors concluded that the findings of this pilot study suggested that SNS is not an effective treatment for chronic anal pain in the majority of patients. Furthermore, PNE is not an effective means of identifying which of these patients are likely to respond to permanent SNS.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes covered if selection criteria are met:

90901
90911
97014
97032

Other CPT codes related to the CPB:

46600
64550
90911

HCPCS codes covered if selection criteria are met:

E0746  Electromyography (EMG), biofeedback device

HCPCS codes not covered for indications listed in the CPB:

J0585  Botulinum toxin type A, per unit
J0586  Injection, Abobotulinumtoxina, 5 units
J0587  Botulinum toxin type B, per 100 units

Other HCPCS codes related to the CPB:

E0745  Neuromuscular stimulator, electronic shock unit
E0761  Non-thermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device
G0283  Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care
L8680  Implantable neurostimulator electrode, each
L8681  Patient programmer (external) for use with implantable
programmable implantable neurostimulator pulse generator
L8682  Implantable neurostimulator radiofrequency receiver
L8683  Radiofrequency transmitter (external) for use with implantable
neurostimulator radiofrequency receiver
L8685  Implantable neurostimulator pulse generator, single array,
rechargeable, includes extension
L8686  Implantable neurostimulator pulse generator, single array, non-
rechargeable, includes extension
L8687  Implantable neurostimulator pulse generator, dual array,
rechargeable, includes extension
L8688  Implantable neurostimulator pulse generator, dual array, non-
rechargeable, includes extension
L8689  External recharging system for battery (internal) for use with
implantable neurostimulator

ICD-9 codes covered if selection criteria are met:

569.42  Anal or rectal pain

The above policy is based on the following references:

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