Clinical Policy Bulletin:
Headaches: Invasive Procedures

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Policy

I. Aetna considers the following interventions experimental and investigational for the treatment of cervicogenic headache because their effectiveness for this indication has not been established:

- Botulinum toxin (however, botulinum toxin is considered medically necessary for chronic migraine headache when criteria in CPB 0113 - Botulinum Toxin are met)
- Cryo-denervation
- Decompressive neck surgery
- Electrical stimulation
- Ganglionectomy
- Local injections of anesthetics or corticosteroids
- Radiofrequency denervation of cervical facet joints

II. Aetna considers the following interventions experimental and investigational for the treatment of occipital neuralgia and other types of headache because their effectiveness for this indication has not been established:

- Auriculotemporal nerve block
- Cervical rhizotomy
- Cryo-denervation
- Decompression of the occipital nerves
- Dorsal column stimulation (see CPB 0194 - Dorsal Column Stimulation)
- Electrical stimulation of the occipital nerve (examples of devices for occipital nerve stimulation are ONSTIM and PRISM)
- Ganglionectomy
- Neurectomy
- Neurolysis of the great occipital nerve with or without section of the inferior oblique muscle
- Neuroplasty
■ Occipital nerve block
■ Resection or partial resection of muscle or tissue from the forehead, peri-orbital, occipital or other facial or scalp areas
■ Supraorbital nerve block
■ Suprascapular nerve block
■ Surgical release of the lesser occipital nerve within the trapezius and other procedures to decompress occipital nerves
■ Thermal neurolysis (thermal and cryodenervation)

III. Aetna considers surgery and the following interventions experimental and investigational for the treatment of cluster headache and other chronic headaches including migraines because their effectiveness for these indications has not been established. Surgical interventions include some of the procedures listed below (not an all-inclusive list):

Ablation or electrical stimulation of the sphenopalatine ganglion (sphenopalatine ganglion block)
Bariatric surgery
Closure of patent foramen ovale
Decompression of the greater occipital, supra-orbital and supra-trochlear nerves
Deep brain stimulation
Gamma knife (stereotactic) radiosurgery
Nerve decompression
Occipital nerve stimulation
Resection of the right and left supra-orbital, supra-trochlear and infra-trochlear nerves
Resection of musculature, including but not limited to the corrugator supercilii muscle, or any soft tissue from the forehead, peri-orbital, occipital or other facial or scalp areas; manipulation or repositioning of any muscle or other soft tissue within these areas
Resection of any portion of the trigeminal nerve or its branches
Suboccipital nerve stimulation
Supraorbital nerve stimulation.

Note: For closure of patent foramen ovale for migraine prophylaxis, see CPB 0292 - Transcatheter Closure of Septal Defects.

Background

Cervicogenic Headache:

Cervicogenic headache (CGH) is a relatively common and still controversial form of headache caused by disease or dysfunction of structures in the cervical spine (e.g., congenital anomalies of the cranio-vertebral junction such as basilar invagination, and atlanto-axial dislocation; injury of the ligaments, muscles, or joints of the neck). It can be triggered by vascular or scar tissue compression of the C2 root and ganglion as well as irritation of other upper cervical nerve roots.
(e.g., C3, C4). In patients with CGH, attacks or chronic fluctuating periods of neck/head pain may be provoked and/or worsened by sustained neck movements or stimulation of ipsilateral tender points. There are no diagnostic imaging techniques of the cervical spine and associated structures that can determine the exact source of pain. Although it has been advocated by some headache clinicians that the use of nerve blocks is an important confirmatory evidence for diagnosing CGH, the standardization of diagnostic nerve blocks in the diagnosis of CGH remains to be defined. Differential diagnoses of CGH include hemicrania continua, chronic paroxysmal hemicrania, occipital neuralgia, migraine headache and tension headache. Moreover, there is considerable overlap in symptoms and findings between CGH and migraine/tension headaches.

A curative treatment for CGH is unlikely to be developed until the etiology of this disorder has been elucidated. Since CGH appears to be refractory to common headache medication, other treatments have been used in the management of CGH. These entail non-invasive therapies such as paracetamol and non-steroidal anti-inflammatory drugs; manual modalities and transcutaneous electrical nerve stimulation; local injections of anesthetic, corticosteroids, or botulinum toxin type A (Botox); as well as invasive surgical therapies such as decompression and radiofrequency lesions of the involved nerve structures (Jansen, 2000; Haldeman and Dagenais, 2001; Martelletti and van Suijlekom, 2004).

In a Cochrane review, Langevin et al (2011) evaluated the literature on the treatment effectiveness of botulinum toxin (BoNT) intra-muscular injections for neck pain, disability, global perceived effect and quality of life in adults with neck pain with or without associated cervicogenic headache, but excluding cervical radiculopathy and whiplash associated disorder. These researchers included randomized and quasi-randomized controlled trials in which BoNT injections were used to treat sub-acute or chronic neck pain. A minimum of 2 review authors independently selected articles, abstracted data, and assessed risk of bias, using the Cochrane Back Review Group criteria. In the absence of clinical heterogeneity, these investigators calculated standardized mean differences (SMD) and relative risks, and performed meta-analyses using a random-effects model. The quality of the evidence and the strength of recommendations were assigned an overall grade for each outcome. They included 9 trials (503 subjects). Only BoNT type A (BoNT-A) was used in these studies. High quality evidence suggested there was little or no difference in pain between BoNT-A and saline injections at 4 weeks (5 trials; 252 subjects; SMD pooled -0.07 (95 % confidence intervals ([CI]: -0.36 to 0.21)) and 6 months for chronic neck pain. Very low quality evidence indicated little or no difference in pain between BoNT-A combined with physiotherapeutic exercise and analgesics and saline injection with physiotherapeutic exercise and analgesics for patients with chronic neck pain at 4 weeks (2 trials; 95 subjects; SMD pooled 0.09 [95 % CI: -0.55 to 0.73]) and 6 months (1 trial; 24 subjects; SMD -0.56 [95 % CI: -1.39 to 0.27]). Very low quality evidence from 1 trial (32 subjects) showed little or no difference between BoNT-A and placebo at 4 weeks (SMD 0.16 [95 % CI: -0.53 to 0.86]) and 6 months (SMD 0.00 [95 % CI: -0.69 to 0.69]) for chronic cervicogenic headache. Very low quality evidence from 1 trial (31 subjects), showed a difference in global perceived effect favouring BoNT-A in chronic neck pain at 4 weeks (SMD -1.12 [95 % CI: -1.89 to -0.36]). The authors concluded that current evidence fails to confirm either a
clinically important or a statistically significant benefit of BoNT-A injection for chronic neck pain associated with or without associated cervicogenic headache. Likewise, there was no benefit seen for disability and quality of life at 4 week and 6 months.

In a review on CGH, Pollmann et al (1997) stated that neither pharmacological nor surgical or chiropractic procedures lead to a significant improvement or remission of CGH. These investigators concluded that until controlled studies on large and homogeneous groups of patients are performed, operative intervention can not be recommended for CGH. Edmeads (2001) noted that although expertly administered local anesthetic blocks applied in a rational fashion can be of diagnostic value, their value as treatment for CGH is much less clear. Furthermore, Evers (2004) stated that for the prophylactic treatment of migraine headache, tension headache, and CGH, no sufficient positive evidence for treatment with Botox is obtained from randomized, double-blind, placebo-controlled trials to date.

Stovner et al (2004) reported on the results of a randomized, double-blind, placebo-controlled study of radiofrequency denervation of facet joints C2 through C6 in cervicogenic headache. A total of 12 patients with disabling, long-standing and treatment-resistant unilateral headache were randomly assigned to receive either sham treatment or radiofrequency neurotomy of facet joints C2 through C6 ipsilateral to the pain. Patients were followed for 2 years by self-assessed pain ratings, measurements of sensitivity to pain and neck mobility measurements for two years following treatment. The investigators reported that subjects treated with neurotomy were somewhat improved by 3 months after treatment, but later there were no marked differences between groups. This led the investigator to conclude that radiofrequency denervation of cervical facet joints is probably not beneficial in cervicogenic headache.

Occipital Neuralgia:

Occipital neuralgia, occurring more often in women than men, is defined as a paroxysmal jabbing pain in the distribution of the greater or lesser occipital nerves. It is characterized by pain in the cervical and posterior areas of the head that may/may not radiate to the sides of the head as well as into the facial and frontal areas. Occipital neuralgia can arise as a result of compression of the greater or lesser occipital nerves, trauma (e.g., whiplash), localized infections or inflammation, gout, diabetes, blood vessel inflammation and local tumors. It may occur as the nerves exit the trapezius or splenius muscle groups. Compression of these nerves may result in a burning dysaesthesias in the occiput with or without radiation behind the ear. Nerve compression can occur from cervical degeneration or post-traumatic compression of the C2 or C3 nerves. The clinical features of the condition are pain and sensory change in the distribution of the relevant nerve, localized nerve trunk tenderness. Clinical signs and symptoms of occipital neuralgia may also be produced by myofascial pain.

Treatments for occipital neuralgia ranges from rest, heat, massage, exercise, antidepressants, nerve blocks, neurectomy, cervical rhizotomy, surgical release of the occipital nerve within the trapezius to neurolysis of the great occipital nerve with or without section of the inferior oblique muscle. However, the effectiveness of many of the invasive procedures has not been firmly established.
Graff-Radford (2001) stated that neurectomy has been employed for occipital neuralgia, but the results are often short-lived. Barolat and Sharan (2000) stated that one of the applications being developed for spinal cord stimulation is occipital neuralgia.

Gille et al (2004) retrospectively evaluated a new surgical treatment consisting of neurolysis of the great occipital nerve and section of the inferior oblique muscle for the treatment of greater occipital neuralgia (n = 10). All the patients had pain exacerbated by flexion of the cervical spine. The average age of the patients was 62 years. The mean follow-up of the series was 37 months. The results of the treatment were assessed according to 3 criteria: (i) degree of pain on a visual analog scale (VAS) before surgery, at 3 months, and at last follow-up; (ii) consumption of analgesics before surgery and at follow-up; and (iii) the degree of patient satisfaction at follow-up. In 3 cases, anatomic anomalies were found -- 1 patient had hypertrophy of the venous plexus around C2; in another, the nerve penetrated the inferior oblique muscle; the 3rd had degenerative C1 to C2 osteoarthritis requiring associated C1 to C2 arthrodesis. The mean VAS score was 80/100 before surgery and 20/100 at last follow-up. Consumption of analgesics decreased in all patients. Seven of the 10 patients were very satisfied or satisfied with the operation. The authors concluded that the new surgical technique provided good results on greater occipital neuralgia if patients are well chosen. The findings by Gille et al (2004) were interesting, but they need to be validated by prospective randomized controlled studies with more patients.

There is a lack of evidence that local injection therapy such as steroids, botulinum toxin and local anesthetics or surgical such as decompression of the C2 nerve root, implantation of spinal cord stimulator, neurolysis of the great occipital nerve and surgical release of the occipital nerve within the trapezius consistently provide sustained pain relief in the majority of patients with CGH and occipital neuralgia. Furthermore, there is also a lack of information regarding which patients might obtain significant benefit from these procedures.

Recently, there has been increased interest in subcutaneous electrical stimulation of the occipital nerve for the treatment of occipital neuralgia. Kapural et al (2005) reported a case series of 6 patients with severe occipital neuralgia who underwent occipital nerve electrical stimulation lead implantation using a modified midline approach. These patients had received conservative and surgical therapies in the past including oral anti-depressants, membrane stabilizers, opioids, occipital nerve blocks, and radiofrequency ablations. Significant decreases in pain VAS scores and drastic improvement in functional capacity were observed during the occipital stimulation trial and during the 3-month follow-up after implantation. The mean VAS score changed from 8.66 +/- 1.0 to 2.5 +/- 1.3 whereas pain disability index improved from 49.8 +/- 15.9 to 14.0 +/- 7.4. These findings need to be validated by randomized controlled studies.

Electrical stimulation of the occipital nerve is also being investigated for the treatment of chronic migraine headaches. However, there is currently a lack of evidence regarding its effectiveness for this indication.

Slavin et al (2006) analyzed records of 14 consecutive patients (9 women and 5 men; mean age of 43.3 years) with intractable occipital neuralgia (ON) treated with
peripheral nerve stimulation (PNS). Five patients had unilateral and 9 had bilateral PNS electrodes inserted for trial, which was considered successful if patient reported at least 50% decrease of pain on the visual analogue scale. Ten patients proceeded with system internalization, and their long-term results were analyzed. At the time of the last follow-up examination (5 to 32 months, mean of 22 months), 7 patients (70%) with implanted PNS systems continue to experience beneficial effects of stimulation, including adequate pain control, continuous employment, and decrease in oral pain medications intake. Two patients had their systems explanted because of loss of stimulation effect or significant improvement of pain, and 1 patient had part of his hardware removed because of infection. The authors concluded that overall, the beneficial effect from chronic stimulation in their series persisted in more than 50% of the patients for whom procedure was considered and in 80% of those who significantly improved during the trial and proceeded with internalization. Thus, chronic PNS may be a safe and relatively effective method for long-term treatment of chronic pain syndrome in patients with medically intractable ON. The results of this small study are promising, but they need to be validated by further investigation.

An interventional procedure consultation from the National Institute for Health and Clinical Excellence (NICE, 2008) concluded: "Current evidence on the safety and efficacy of occipital nerve stimulation for intractable headache is inadequate in both quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research."

Kapural et al (2007) retrospectively described a series of 6 patients with severe occipital neuralgia who received conservative and interventional therapies, including oral anti-depressants, membrane stabilizers, opioids, and traditional occipital nerve blocks without significant relief. This group then underwent occipital nerve blocks using the botulinum toxin type A (BoNT-A) Botox type A (50 U for each block; 100 U if bilateral). Significant decreases in pain VAS scores and improvement in Pain Disability Index (PDI) were observed at 4 weeks follow-up in 5 out of 6 patients following BoNT-A occipital nerve block. The mean VAS score changed from 8 +/- 1.8 (median score of 8.5) to 2 +/- 2.7 (median score of 1), while PDI improved from 51.5 +/- 17.6 (median of 56) to 19.5 +/- 21 (median of 17.5) and the duration of the pain relief increased to an average of 16.3 +/- 3.2 weeks (median of 16) from an average of 1.9 +/- 0.5 weeks (median of 2) compared to diagnostic 0.5% bupivacaine block. Following block resolution, the average pain scores and PDI returned to similar levels as before BoNT-A block. The authors concluded that BoNT-A occipital nerve blocks provided a much longer duration of analgesia than diagnostic local anesthetics. The functional capacity improvement measured by PDI was profound enough in the majority of the patients to allow patients to resume their regular daily activities for a period of time. This was a retrospective, small study with short-term follow-up; its findings need to be validated by well-designed studies.

In a review on greater occipital nerve blockade, Selkler (2008) stated that studies regarding greater occipital nerve injection in primary headaches began with Michael Anthony and almost all the studies today accept Anthony's studies as reference work. Although more than 20 years had passed, there is insufficient information about this procedure. According to available evidence, steroids are apparently effective in both preventive as well as therapy (for acute attack) in
cluster headaches. Effectiveness of occipital nerve blocks for the treatment of migraine headaches is not as dramatic as that observed for cluster headaches. Despite the fact that local anesthetics has a role in relieving acute attacks, single injection is unsuitable as prophylaxis. The authors concluded that although there are case reports regarding the effectiveness of occipital nerve blocks in relieving acute pain in cluster headaches and migraine headaches, there is a need for systematized clinical studies.

Ducic et al (2009) presented the largest reported series of surgical neurolysis of the greater occipital nerve in the management of occipital neuralgia. A retrospective chart review was conducted to identify 206 consecutive patients undergoing neurolysis of the greater or, less commonly, excision of the greater and/or lesser occipital nerves. Pre-operative and post-operative VAS and migraine headache indices were measured. Success was defined as a reduction in pain of 50 % or greater. Of 206 patients, 190 underwent greater occipital nerve neurolysis (171 bilateral); 12 patients underwent greater and lesser occipital nerve excision, whereas 4 underwent lesser occipital nerve excision alone. The authors found that 80.5 % of patients experienced at least 50 % pain relief and 43.4 % of patients experienced complete relief of headache. Mean pre-operative pain score was 7.9 +/- 1.4. Mean post-operative pain was 1.9 +/- 1.8. Minimum duration of follow-up was 12 months. There were 2 minor complications. The authors concluded that neurolysis of the greater occipital nerve appears to provide safe, durable pain relief in the majority of selected patients with chronic headaches caused by occipital neuralgia. The drawbacks of this study were the retrospective, uncontrolled, and non-blinded nature of the study. Well-designed studies are especially important for studying interventions for pain, due to placebo effects, the waxing and waning nature of the condition, and the potential effects of other concurrent treatments on the person's pain.

In a prospective, randomized cross-over study, Serra and Marchioretto (2012) investigated the safety and effectiveness of occipital nerve stimulation (ONS) for chronic migraine (CM) and medication overuse headache (MOH) patients and evaluated changes in disability, quality of life, and drug intake in implanted patients. Eligible patients who responded to a stimulation trial underwent device implantation and were randomized to "Stimulation On" and "Stimulation Off" arms. Patients crossed-over after 1 month, or when their headaches worsened. Stimulation was then switched On for all patients. Disability as measured by the Migraine Disability Assessment (MIDAS), quality of life (SF-36), and drug intake (patient's diary) were assessed over a 1-year follow-up. A total of 34 patients (76 % women, 34 % men, mean age of 46 +/- 11 years) were enrolled; 30 were randomized and 29 completed the study. Headache intensity and frequency were significantly lower in the On arm than in the Off arm (p < 0.05) and decreased from the baseline to each follow-up visit in all patients with Stimulation On (median MIDAS A and B scores: baseline = 70 and 8; 1-year follow-up = 14 and 5, p < 0.001). Quality of life significantly improved (p < 0.05) during the study. Triptans and non-steroidal anti-inflammatory drug use fell dramatically from the baseline (20 and 25.5 doses/month) to each follow-up visit (3 and 2 doses/month at 1 year, p < 0.001). A total of 5 adverse events occurred: 2 infections and 3 lead migrations. The authors concluded that according to the results obtained, ONS appears to be a safe and effective treatment for carefully selected CM and MOH patients. The drawbacks of this study were single-center study, relatively small
number of patients, and absence of a control group. The authors stated that
further analyses on larger populations in multi-center trials may strengthen these
promising findings.

Vadivelu et al (2012) reviewed retrospectively their experience with ONS in
patients with a primary diagnosis of Chiari malformation and a history of chronic
occipital pain intractable to medical and surgical therapies. They presented a
retrospective analysis of 22 patients with Chiari malformation and persistent
occipital headaches who underwent occipital neurostimulator trials and, after
successful trials, permanent stimulator placement. A trial was considered
successful with greater than 50 % pain relief as assessed with a standard VAS
score. Patients with a successful trial underwent permanent placement
approximately 1 to 2 weeks later. Patients were assessed post-operatively for
pain relief via the VAS. Sixty-eight percent of patients (15 of 22) had a successful
stimulator trial and proceeded to permanent implantation. Of those implanted, 87
% (13 of 15) reported continued pain relief at a mean follow-up of 18.9 months
(range of 6 to 51 months). Device-related complications requiring additional
surgeries occurred in 40 % of patients. The authors concluded that ONS may
provide significant long-term pain relief in selected Chiari I malformation patients
with persistent occipital pain. Moreover, they stated that larger and longer-term
studies are needed to further define appropriate patient selection criteria and to
refine the surgical technique to minimize device-related complications.

Acar et al (2008) noted that surgical removal of the second (C2) or third (C3)
cervical sensory dorsal root ganglion is an option to treat occipital neuralgia (ON).
These investigators evaluated the short-term and the long-term effectiveness of
these procedures for management of cervical and occipital neuropathic pain. A
total of 20 patients (mean age of 48.7 years) were identified who had undergone
C2 and/or C3 ganglionectomies for intractable occipital pain and a retrospective
chart review undertaken. Patients were interviewed regarding pain relief, pain
relief duration, functional status, medication usage and procedure satisfaction, pre-
operatively, immediately post-operative, and at follow-up (mean of 42.5 months).
C2, C3 and consecutive ganglionectomies at both levels were performed on 4, 5,
and 11 patients, respectively. All patients reported pre-operative pain relief
following cervical nerve blocks. Average VAS scores were 9.4 pre-operatively and
2.6 immediately after procedure. Ninety-five percent of patients reported short-
term pain relief (less than 3 months). In 13 patients (65 %), pain returned after an
average of 12 months (C2 ganglionectomy) and 8.4 months (C3 ganglionectomy).
Long-term results were excellent, moderate, and poor in 20, 40 and 40 % of
patients, respectively. Cervical ganglionectomy offers relief to a majority of
patients, immediately after procedure, but the effect is short-lived. Nerve blocks
are helpful in predicting short-term success, but a positive block result does not
necessarily predict long-term benefit and therefore can not justify surgery by itself.
However, since 60 % of patients report excellent-moderate results, cervical
ganglionectomy continues to have a role in the treatment of intractable ON. The
findings of this small study need to be validated by well-designed studies.

Pisapia and colleagues (2012) examined the effectiveness of C2 nerve root
decompression and C2 dorsal root ganglionectomy for intractable ON and C2
ganglionectomy after pain recurrence following initial decompression. A
retrospective review was performed of the medical records of patients undergoing
surgery for ON. Pain relief at the time of the most recent follow-up was rated as excellent (headache relieved), good (headache improved), or poor (headache unchanged or worse). Telephone contact supplemented chart review, and patients rated their pre-operative and post-operative pain on a 10-point numeric scale. Patient satisfaction and disability were also examined. Of 43 patients, 29 (67 %) were available for follow-up after C2 nerve root decompression (n = 11), C2 dorsal root ganglionectomy (n = 10), or decompression followed by ganglionectomy (n = 8). Overall, 19 of 29 patients (66 %) experienced a good or excellent outcome at most recent follow-up. Among the 19 patients who completed the telephone questionnaire (mean follow-up of 5.6 years), patients undergoing decompression, ganglionectomy, or decompression followed by ganglionectomy experienced similar outcomes, with mean pain reduction ratings of 5 +/- 4.0, 4.5 +/- 4.1, and 5.7 +/- 3.5. Of 19 telephone responders, 13 (68 %) rated overall operative results as very good or satisfactory. The authors concluded that in the third largest series of surgical intervention for ON, most patients experienced favorable post-operative pain relief. For patients with pain recurrence after C2 decompression, salvage C2 ganglionectomy is a viable surgical option and should be offered with the potential for complete pain relief and improved quality of life. Only 10 patients with C2 dorsal root ganglionectomy were available for follow-up. The moderate rate of follow-up (67 %) may have skewed these results.

Also, UpToDate reviews on “Occipital neuralgia” (Garza, 2012) and “Cervicogenic headache” (Biondi and Bajwa, 2012) do not mention the use of cryo-denervation and ganglionectomy.

The supraorbital nerve is located on the front of the face over the eyebrow. It supplies sensory innervation to the upper eyelid, forehead, and scalp, extending almost to the lambdoidal suture. A nerve block is a procedure in which an anesthetic agent is injected directly near a nerve to block pain. It is a form of regional anesthesia.

Cluster Headache:

Cluster headaches are characterized by repeated attacks of severe headache usually occurring several times a day. Patients with chronic cluster headache have unremitting illness that requires daily preventive medical treatment for years. Burns et al (2007) examined the effectiveness of occipital nerve stimulation (ONS) in the treatment of patients with refractory chronic cluster headache (n = 8). Electrodes were implanted in the suboccipital region for ONS. Other than the first patient, who was initially stimulated unilaterally before being stimulated bilaterally, all patients were stimulated bilaterally during treatment. At a median follow-up of 20 months (range of 6 to 27 months for bilateral stimulation), 6 of 8 patients reported responses that were sufficiently meaningful for them to recommend the treatment to similarly affected patients with chronic cluster headache. Two patients noticed a substantial improvement (90 % and 95 %) in their attacks; 3 patients noticed a moderate improvement (40 %, 60 %, and 20 to 80 %, respectively) and 1 reported mild improvement (25 %). Improvements occurred in both frequency and severity of attacks. These changes took place over weeks or months, although attacks returned in days when the device malfunctioned (e.g., with battery depletion). Adverse effects were lead migrations in 1 patient and
battery depletion requiring replacement in 4. The authors concluded that ONS in cluster headache seems to offer a safe, effective treatment option that could begin a new era of neurostimulation therapy for primary headache syndromes.

In a pilot study, Magis et al (2007) evaluated the effectiveness of ONS in the treatment of patients with drug-resistant chronic cluster headache (dCCH). A total of 8 patients with dCCH had a sub-occipital neurostimulator implanted on the side of the headache and were asked to record details of frequency, intensity, and symptomatic treatment for their attacks in a diary before and after continuous ONS. To detect changes in cephalic and extra-cephalic pain processing, these researchers measured electrical and pressure pain thresholds and the nociceptive blink reflex. Two patients were pain-free after a follow-up of 16 and 22 months; 1 of them still had occasional autonomic attacks. Three patients had around a 90% reduction in attack frequency. Two patients, 1 of whom had had the implant for only 3 months, had improvement of around 40%. Mean follow-up was 15.1 months (standard deviation of 9.5, range of 3 to 22 months). Intensity of attacks tends to decrease earlier than frequency during ONS and, on average, is improved by 50% in remaining attacks. All but 1 patient were able to substantially reduce their preventive drug treatment. Interruption of ONS by switching off the stimulator or because of an empty battery was followed within days by recurrence and increase of attacks in all improved patients. Occipital nerve stimulation did not significantly modify pain thresholds. The amplitude of the nociceptive blink reflex increased with longer durations of ONS. There were no serious adverse events. The authors concluded that ONS could be an efficient treatment for dCCH and could be safer than deep hypothalamic stimulation. The delay of 2 months or more between implantation and significant clinical improvement suggests that the procedure acts via slow neuromodulatory processes at the level of upper brain stem or diencephalic centers.

In a retrospective analysis, Schwedt et al (2007) examined the safety and effectiveness of ONS for medically intractable headache. Pre- and post-implantation data regarding headache frequency, severity, disability, depression and post-stimulator complications were collected. A total of 15 patients (12 females and 3 males) with age ranging from 21 to 52 years (mean of 39 years) were included in this study. Eight patients had chronic migraine, 3 chronic cluster, 2 hemicrania continua and 2 had post-traumatic headache. Eight patients underwent bilateral and 7 had unilateral lead placement. They were measured after 5 to 42 months (mean of 19 months). All 6 mean headache measures improved significantly from baseline (p < 0.03). Headache frequency per 90 days improved by 25 days from a baseline of 89 days; headache severity (0 to 10) improved 2.4 points from a baseline of 7.1 points; MIDAS disability improved 70 points from a baseline of 179 points; HIT-6 scores improved 11 points from a baseline of 71 points; BDI-II improved 8 points from a baseline of 20 points; and the mean subjective percent change in pain was 52%. Most patients (60%) required lead revision within 1 year. One patient required generator revision. The authors concluded that ONS may be effective in some patients with intractable headache. Surgical revisions may be commonly required. They noted that safety and effectiveness results from prospective, randomized, sham-controlled studies in patients with medically refractory headache are needed to validate these preliminary findings.
Jasper and Hayek (2008) noted that there is limited evidence that ONS is a useful tool in the treatment of chronic severe headaches. In a review on ONS for headache, Goadsby et al (2008) stated that far from proven and with much work to be done, neurostimulation therapy by means of ONS is an exciting potential development for patients and doctors. Furthermore, Trentman and Zimmerman (2008) stated that ONS may be an effective minimally invasive treatment modality for refractory headache disorders; however, further studies are needed.

Burns et al (2009) described the clinical outcome of ONS for 14 patients with intractable CCH. A total of 14 patients with medically intractable CCH were implanted with bilateral electrodes in the suboccipital region for ONS and a retrospective assessment of their clinical outcome were obtained. At a median follow-up of 17.5 months (range of 4 to 35 months), 10 of 14 patients reported improvement and 9 of these recommended ONS. Three patients noticed a marked improvement of 90% or better (90%, 90%, and 95%, respectively), 3 a moderate improvement of 40% or better (40%, 50%, and 60%, respectively), and 4 a mild improvement of 20 to 30% (20%, 20%, 25%, and 30%, respectively). Improvement occurred within days to weeks for those who responded most and patients consistently reported their attacks returned within hours to days when the device was off. One patient found that ONS helped abort acute attacks. Adverse events of concern were lead migrations and battery depletion. The authors concluded that intractable CCH is a devastating, disabling condition that has traditionally been treated with cranially invasive or neurally destructive procedures. Occipital nerve stimulation offers a safe, effective option for some patients with CCH. However, they stated that more work is needed to evaluate and understand this novel therapy.

Narouze (2010) stated that cluster headache is a strictly unilateral head pain that is associated with cranial autonomic symptoms and usually follows circadian and circannual patterns. Chronic cluster headache, which accounts for about 10% to 15% of patients with cluster headache, lacks the circadian pattern and is often resistant to pharmacological management. The sphenopalatine ganglion (SPG), located in the pterygopalatine fossa, is involved in the pathophysiology of cluster headache and has been a target for blocks and other surgical approaches. Percutaneous radiofrequency ablation of the SPG was shown to have encouraging results in those patients with intractable cluster headaches.

Ansarinia et al (2010) examined the effects of electrical stimulation of SPG for acute treatment of cluster headaches. A total of 6 patients with refractory CCH were treated with short-term (up to 1 hour) electrical stimulation of the SPG during an acute cluster headache. Headaches were spontaneously present at the time of stimulation or were triggered with agents known to trigger clusters headache in each patient. A standard percutaneous infra-zygomatic approach was used to place a needle at the ipsilateral SPG in the pterygopalatine fossa under fluoroscopic guidance. Electrical stimulation was performed using a temporary stimulating electrode. Stimulation was performed at various settings during maximal headache intensity. Five patients had cluster headaches during the initial evaluation. Three returned 3 months later for a second evaluation. There were 18 acute and distinct cluster headache attacks with clinically maximal VAS intensity of 8 (out of 10) and above. Electrical stimulation of SPG resulted in complete...
resolution of the headache in 11 attacks, partial resolution (greater than 50 % VAS reduction) in 3, and minimal to no relief in 4 attacks. Associated autonomic features of cluster headache were resolved in each responder. Pain relief was noted within several minutes of stimulation. The authors concluded that SPG stimulation can be effective in relieving acute severe cluster headache pain and associated autonomic features. They stated that chronic long-term outcome studies are needed to determine the utility of SPG stimulation for management and prevention of cluster headaches.

In a prospective, cross-over, double-blind, multi-center study, Fontaine et al (2010) evaluated the safety and effectiveness of unilateral hypothalamic deep brain stimulation (DBS) in 11 patients with severe refractory CCH. The randomized phase compared active and sham stimulation during 1-month periods, and was followed by a 1-year open phase. The severity of CCH was assessed by the weekly attacks frequency (primary outcome), pain intensity, sumatriptan injections, emotional impact (HAD) and quality of life (SF12). Tolerance was assessed by active surveillance of behavior, homeostatic and hormonal functions. During the randomized phase, no significant change in primary and secondary outcome measures was observed between active and sham stimulation. At the end of the open phase, 6/11 responded to the chronic stimulation (weekly frequency of attacks decrease [50 %]), including 3 pain-free patients. There were 3 serious adverse events, including subcutaneous infection, transient loss of consciousness and micturition syncopes. No significant change in hormonal functions or electrolytic balance was observed. Randomized phase findings of this study did not support the effectiveness of DBS in refractory CCH, but open phase findings suggested long-term effectiveness in more than 50 % patients, confirming previous data, without high morbidity. Discrepancy between these findings justifies additional controlled studies.

Other Headaches:

Asensio-Samper and colleagues (2008) presented the case of a patient with headache because of post-traumatic supra-orbital neuralgia, refractory to medical treatment, with good analgesic control following peripheral nerve stimulation. The authors stated that peripheral nerve stimulation may be considered a safe, reversible treatment for patients with headache secondary to supra-orbital neuralgia who respond poorly to pharmacological treatment, thus avoiding irreversible alternatives such as surgery. Moreover, in a review on neurostimulation in chronic cluster headache, Magis and Schoenen (2008) noted that recent case reports mentioned effectiveness of supra-orbital and vagus nerve stimulation. Whether these methods have a place in the management of patients with intractable chronic cluster headache remains to be determined.

Mathew (2009) stated that comparator studies that assess treatment effects in a clinical setting have improved the understanding of the efficacy and tolerability of prophylactic treatments for chronic migraine. It is premature to recommend device-based treatments, such as ONS, vagal nerve stimulation, and patent foramen ovale closure for chronic migraine, because clinical trials are still in the preliminary stages.

Franzini et al (2009) stated that ONS is an emerging procedure for the treatment of cranio-facial pain syndromes and headaches refractory to conservative
treatments. Paemeleire and Bartsch (2010) stated that ONS was originally described in the treatment of occipital neuralgia. However, the spectrum of possible indications has expanded in recent years to include primary headache disorders, such as migraine and cluster headaches. Retrospective and some prospective studies have yielded encouraging results, and evidence from controlled clinical trials is emerging. Moreover, these researchers noted that ONS is far from a standardized technique at the moment. They reviewed the recent literature on the topic, both with respect to the procedure and its possible complications. An important way to move forward in the scientific evaluation of occipital nerve stimulation to treat refractory headache is the clinical phenotyping of patients to identify patients groups with the highest likelihood to respond to this modality of treatment. This requires multi-disciplinary assessment of patients. The development of occipital nerve stimulation as a new treatment for refractory headache offers an exciting prospect to treat the most disabled headache patients. Data from ongoing controlled trials will shed new light on some of the unresolved questions.

In a retrospective, descriptive study, Poggi et al (2008) evaluated the effectiveness of surgical decompression of multiple migraine trigger sites in a clinical practice setting, and compared the results to those previously published. A total of 18 patients who had undergone various combinations of surgical decompression of the supraorbital, supratrochlear, and greater occipital nerves and zygomaticotemporal neurectomy were included in this analysis. All patients had been diagnosed with migraine headaches according to neurological evaluation and had undergone identification of trigger sites by botulinum toxin type A injections. Following surgical decompression, the number of migraines per month and the pain intensity of migraine headaches decreased significantly. Three patients (17 %) had complete relief of their migraines, and 9 of 18 (50 %) had at least a 75 % reduction in the frequency, duration, or intensity of migraines; and 39 % of patients have discontinued all migraine medications. Mean follow-up was 16 months (range of 6 to 41 months) after surgery. All subjects stated they would repeat the surgical procedure. The authors concluded that the findings of this study supported the theory that peripheral nerve compression triggers a migraine cascade. They verified a reduction in duration, intensity, and frequency of migraine headaches by surgical decompression of the supraorbital, supratrochlear, zygomaticotemporal, and greater occipital nerves. They stated that a significant amount of patient screening is needed for proper patient selection and trigger site identification for surgical success. These findings need to be validated by well-designed studies.

Kung et al (2011) stated that migraine headache can be a debilitating condition that confers a substantial burden to the affected individual and to society. Despite significant advancements in the medical management of this challenging disorder, clinical data have revealed a proportion of patients who do not adequately respond to pharmacologic intervention and remain symptomatic. Recent insights into the pathogenesis of migraine headache argue against a central vasogenic cause and substantiate a peripheral mechanism involving compressed craniofacial nerves that contribute to the generation of migraine headache. Botulinum toxin injection is a relatively new treatment approach with demonstrated efficacy and supports a peripheral mechanism. Patients who fail optimal medical management and experience amelioration of headache pain after injection at specific anatomical
locations can be considered for subsequent surgery to decompress the entrapped peripheral nerves. Migraine surgery is an exciting prospect for appropriately selected patients suffering from migraine headache and will continue to be a burgeoning field that is replete with investigative opportunities. The authors stated that future research will elucidate the anatomical relationships of migraine trigger points and possibly identify additional sites that have the capacities to generate migraines. Research is currently being conducted to examine the long-term benefits of migraine surgery.

Magis and Schoenen (2011) reviewed the latest clinical trial results in anti-migraine treatment. The oral calcitonine gene-related peptide antagonist telcagepant is effective in acute treatment. Compared to triptans, its effectiveness is almost comparable but its tolerance is superior. The same is true for the 5HT-1F agonist lasmiditan. Triptans, as other drugs, are more efficient if taken early but NSAIDs and analgesics remain useful for acute treatment, according to several meta-analyses. Single-pulse transcranial magnetic stimulation during the aura rendered more patients pain-free (39%) than sham stimulation (22%) in 1 study. Topiramate could be effective for migrainous vertigo, but it did not prevent transformation to chronic migraine in patients with high attack frequency.

Onabotulinumtoxin A was effective for chronic migraine and well tolerated, but the therapeutic gain over placebo was modest; the clinical profile of responders remains to be determined before widespread use. Occipital nerve stimulation was effective in intractable chronic migraine with 39% of responders compared to 6% after sham stimulation. This and other neuromodulation techniques, such as sphenopalatine ganglion stimulation, are promising treatments for medically refractory patients; but large controlled trials are needed. One study suggested that outcome of patent foramen ovale closure in migraine might depend on anatomic and functional characteristics.

In a prospective, observational study, Bond et al (2011) examined if weight loss after bariatric surgery is associated with improvements in migraine headaches. A total of 24 patients who had migraine according to the ID-Migraine screener were assessed before and 6 months after bariatric surgery. At both time points, patients had their weight measured and reported on frequency of headache days, average headache pain severity, and headache-related disability over the past 90 days via the Migraine Disability Assessment questionnaire. Changes in headache measures and the relation of weight loss to these changes were assessed using paired-sample t tests and logistic regression, respectively. Patients were mostly female (88%), middle-aged (mean age of 39.3), and severely obese (mean body mass index of 46.6) at baseline. Mean (+/- SD) number of headache days was reduced from 11.1 +/- 10.3 pre-operatively to 6.7 +/- 8.2 post-operatively (p < 0.05), after a mean percent excess weight loss (% EWL) of 49.4%. The odds of experiencing a greater than or equal to 50% reduction in headache days was related to greater % EWL, independent of surgery type (p < 0.05). Reductions in severity were also observed (p < 0.05) and the number of patients reporting moderate-to-severe disability decreased from 12 (50.0%) before surgery to 3 (12.5%) after surgery (p < 0.01). The authors concluded that severely obese migraineurs experience marked alleviation of headaches following significant weight reduction via bariatric surgery. They stated that future studies are needed to determine whether more modest, behaviorally produced weight losses can result in similar migraine improvements. Limitations of this study included its
observational nature, small number of patients, and the lack of a control group. It would also be interesting to determine if there is a dose-response relationship (i.e., whether greater weight loss results in greater improvement).

Gaul et al (2011) noted that cluster headache is the most common type of trigemino-autonomic headache, affecting approximately 120,000 persons in Germany alone. The attacks of pain are in the peri-orbital area on one side, last 90 minutes on average, and are accompanied by trigemino-autonomic manifestations and restlessness. Most patients have episodic cluster headache; about 15% have chronic cluster headache, with greater impairment of their quality of life. The attacks often possess a circadian and seasonal rhythm. Oxygen inhalation and triptans are effective acute treatment for cluster attacks. First-line drugs for attack prophylaxis include verapamil and cortisone; alternatively, lithium and topiramate can be given. Short-term relief can be obtained by the subcutaneous infiltration of local anesthetics and steroids along the course of the greater occipital nerve, although most of the evidence in favor of this is not derived from randomized clinical trials. Patients whose pain is inadequately relieved by drug treatment can be offered newer, invasive treatments, such as deep brain stimulation in the hypothalamus (DBS) and bilateral ONS. The authors concluded that pharmacotherapy for the treatment of acute attacks and for attack prophylaxis is effective in most patients. For the minority who do not gain adequate relief, newer invasive techniques are available in some referral centers. Definitive conclusions as to their value cannot yet be drawn from the available data.

The Work Loss Data Institute's clinical guideline on "Neck and upper back (acute & chronic)" (2011) listed greater occipital nerve block (diagnostic and therapeutic) as one of the interventions/procedures that are under study and are not specifically recommended.

The Institute for Clinical Systems Improvement's clinical practice guideline on "Diagnosis and treatment of headache" (2011) does not mention the use of decompression of the occipital/greater occipital, supra-orbital and supra-trochlear nerves. Furthermore, an UpToDate review on "Overview of chronic daily headache" (Garza and Schwedt, 2012) does not mention the use of decompression of the occipital, supra-orbital and supra-trochlear nerves as a therapeutic option.

Saper et al (2011) presented preliminary safety and efficacy data on ONS in patients with medically intractable CM. Eligible subjects received an occipital nerve block, and responders were randomized to adjustable stimulation (AS), preset stimulation (PS) or medical management (MM) groups. Seventy-five of 110 subjects were assigned to a treatment group; complete diary data were available for 66. A responder was defined as a subject who achieved a 50% or greater reduction in number of headache days per month or a 3-point or greater reduction in average overall pain intensity compared with baseline. Three-month responder rates were 39% for AS, 6% for PS and 0% for MM. No unanticipated adverse device events occurred. Lead migration occurred in 12 of 51 (24%) subjects. The authors concluded that results of this feasibility study offer promise and should prompt further controlled studies of ONS in CM.

In an editorial that accompanied the afore-mentioned study, Schwedt (2011) stated that the findings by Saper et al suggested that ONS is a promising
treatment for CM and that further clinical trials are needed. Schwedt noted several drawbacks of the study -- (i) patients were taking migraine prophylactic medications; the effects of these medications on study results cannot be determined, (ii) high complication rates -- 24% of subjects had lead migration and 14% had infection, (iii) short-term follow-up -- this study only reported 3 months of follow-up; the need for battery replacement has to be considered when discussing stimulator therapy, and (iv) only 39% of subjects had benefits that met a priori criteria for response. Schwedt stated that if ONS is to be considered a viable therapy, benefits must be persistent over a prolonged duration of time with acceptable complication rates and battery life.

Strand et al (2011) evaluated the effectiveness of a microstimulator for chronic cluster headache. Four patients with medically refractory chronic cluster headache underwent implantation of a unilateral Bion microstimulator. In-person follow-up was conducted for 12 months after implantation, and a prospective follow-up chart review was carried out to assess long-term outcome. Three of the participants returned their headache diaries for evaluation. The mean duration of chronic cluster headache was 14.3 years (range of 3 to 29 years). Pain was predominantly or exclusively retro-ocular/peri-ocular. One participant showed a positive response (greater than 50% reduction in cluster headache frequency) at 3 months post-implant, while there were 2 responders at 6 months. At least 1 of the participants continued to show greater than 60% reduction in headache frequency at 12 months. A chart review showed that at 58 to 67 months post-implant, all 3 participants reported continued use and benefit from stimulation. No side-shift in attacks was noted in any participant. Adverse events were limited to 2 participants with neck pain and/or cramping with stimulation at high amplitudes; one required revision for a faulty battery. The authors concluded that unilateral occipital nerve stimulation, using a minimally invasive microstimulator, may be effective for the treatment of medically refractory chronic cluster headache. This benefit may occur immediately after implantation, remain sustained up to 5 years after implantation, and occur despite the anterior location of the pain. They stated that prospective, randomized controlled trials of occipital nerve stimulation (ONS) in chronic cluster headache should proceed.

Lambru and Matharu (2012) stated that advances in the management of headache disorders have meant that a substantial proportion of patients can be effectively treated with medical treatments. However, a significant minority of these patients are intractable to conventional medical treatments. Occipital nerve stimulation is emerging as a promising treatment for patients with medically intractable, highly disabling chronic headache disorders, including migraine, cluster headache and other less common headache syndromes. Open-label studies have suggested that this treatment modality is effective and recent controlled trial data are also encouraging. The procedure is performed using several technical variations that have been reviewed along with the complications, which are usually minor and tolerable. The mechanism of action is poorly understood, though recent data suggest that ONS could restore the balance within the impaired central pain system through slow neuromodulatory processes in the pain neuromatrix. While the available data are very encouraging, the ultimate confirmation of the utility of a new therapeutic modality should come from controlled trials before widespread use can be advocated; more controlled data are still needed to properly assess the role of ONS in the management of medically intractable headache disorders. The
authors concluded that future studies also need to address the variables that are predictors of response, including clinical phenotypes, surgical techniques and stimulation parameters.

Presently, the Food and Drug Administration (FDA) has not approved any device for ONS. Clinical trials are currently underway for 2 ONS devices -- ONSTIM® (Medtronic Neuro) and PRISM® (Boston Scientific Corporation) -- to ascertain the safety and effectiveness of ONS for migraine headaches.

The Taiwan Headache Society's treatment guidelines for “Acute and preventive treatment of cluster headache” (Chen et al, 2011) evaluated both the acute and the preventive treatments for cluster headache now being used in Taiwan, based on the principles of evidence-based medicine. These investigators assessed the quality of clinical trials and levels of evidence, and referred to other treatment guidelines proposed by other countries. Throughout several panel discussions, these researchers merged opinions from the subcommittee members and proposed a consensus on the major roles, recommended levels, clinical efficacy, adverse events and cautions of clinical practice regarding acute and preventive treatments of cluster headache. The majority of Taiwanese patients have episodic cluster headaches, because chronic clusters are very rare. Cluster headache is characterized by severe and excruciating pain which develops within a short time and is associated with ipsilateral autonomic symptoms. Therefore, emergency treatment for a cluster headache attack is extremely important. Within the group of acute medications currently available in Taiwan, the subcommittee determined that high-flow oxygen inhalation has the best evidence of effectiveness, followed by intra-nasal triptans. Both are recommended as 1st-line medical treatments for acute attacks. Oral triptans were determined to be 2nd-line medications. For transitional prophylaxis, oral corticosteroids are recommended as the 1st-line medication, and ergotamine as the 2nd-line choice. As for maintenance prophylaxis, verapamil has the best evidence and is recommended as the 1st-line medication. Lithium, melatonin, valproic acid, topiramate and gabapentin are suggested as the 2nd-line preventive medications. Surgical interventions, including ONS, DBS, radiofrequency block of the sphenopalatine ganglion, percutaneous radiofrequency rhizotomy and trigeminal nerve section, are invasive and their long-term effectiveness and adverse events are still not clear in Taiwanese patients; therefore, they are not recommended currently by the subcommittee. The transitional and maintenance prophylactic medications can be used together to attain treatment effectiveness. Once the maintenance prophylaxis achieves effectiveness, the transitional prophylactic medications can be tapered gradually. The authors suggested corticosteroids be used within 2 weeks, if possible. The duration of maintenance treatment depends on the individual patient's clinical condition, and the medications can be tapered off when the cluster period is over.

Also, the National Clinical Guideline Centre’s guideline on “Headaches: Diagnosis and management of headaches in young people and adults” (NICE, 2012) as well as the Institute for Clinical Systems Improvement’s clinical guideline on “Diagnosis and treatment of headache” (Beithon et al, 2013) did not mention surgery as a therapeutic option.
Furthermore, an UpToDate review on “Chronic migraine” (Garza and Schwedt, 2014) states that “Occipital nerve stimulation -- There are inconsistent data from small randomized trials regarding the benefit of occipital nerve stimulation for the treatment of chronic migraine. In the largest trial, there was no significant difference at 12 weeks for the primary endpoint, the percentage of patients that had a ≥ 50 percent reduction in mean daily pain score in the active compared with the control group. However, there were statistically significant if modest improvements with active stimulation for a number of secondary endpoints, including the percentage of patients with a ≥ 30 percent reduction in mean daily pain score, and reduction in the mean number of headache days and migraine-related disability. The findings from these reports are limited by concerns about blinding in the control (sham treatment) groups, given that active treatment causes paresthesia, and relatively high rates of complications, including lead migration in 14 to 24 percent of subjects. Further trials are needed to determine if occipital nerve stimulation is a useful therapy for chronic migraine”. This review also does not mention the use of surgical interventions as therapeutic options.

Lip and Lip (2014) identified the extent of patent foramen ovale prevalence in migraineurs and examined if closure of a patent foramen ovale would improve migraine headache. An electronic literature search was performed to select studies between January 1980 and February 2013 that were relevant to the prevalence of patent foramen ovale and migraine, and the effects of intervention(s) on migraine attacks. Of the initial 368 articles presented by the initial search, 20 satisfied the inclusion criteria assessing patent foramen ovale prevalence in migraineurs and 21 presented data on patent foramen ovale closure. In case series and cohort studies, patent foramen ovale prevalence in migraineurs ranged from 14.6 % to 66.5 %. Case-control studies reported a prevalence ranging from 16.0 % to 25.7 % in controls, compared with 26.8 % to 96.0 % for migraine with aura. The extent of improvement or resolution of migraine headache attack symptoms varied. In case series, intervention ameliorated migraine headache attack in 13.6 % to 92.3 % of cases. One single randomized trial did not show any benefit from patent foramen ovale closure. The overall data did not exclude the possibility of a placebo effect for resolving migraine following patent foramen ovale closure. The authors concluded that this systematic review demonstrated firstly that migraine headache attack is associated with a higher prevalence of patent foramen ovale than among the general population. Moreover, observational data suggested that some improvement of migraine would be observed if the patent foramen ovale were to be closed. They stated that a proper assessment of any interventions for patent foramen ovale closure would require further large randomized trials to be conducted given uncertainties from existing trial data.

CPT Codes / ICD-9 Codes / HCPCS Codes

_Cervicogenic, cluster and other chronic headaches:

CPT codes not covered for indications listed in the CPB:

_There is no specific code for Ganglionectomy:_

43631 - 43635
Gastrectomy, partial, distal, or vagotomy when performed with partial distal gastrectomy

43644 - 43645
Laparoscopy, surgical gastric restrictive procedure [gastric bypass]

43770 - 43775
Laparoscopy, surgical gastric restrictive procedure [gastric restrictive device]

43842 - 43848
Gastric restrictive procedure, without gastric bypass, for morbid obesity, or gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch), or gastric restrictive procedure, with gastric bypass for morbid obesity, or revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)

43886 - 43888
Gastric restrictive procedure, open

61796
Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 simple cranial lesion [auriculotemporal nerve block]

+61797
each additional cranial lesion, simple (List separately in addition to code for primary procedure) [auriculotemporal nerve block]

+61798
1 complex cranial lesion [auriculotemporal nerve block]

+61799
each additional cranial lesion, complex (List separately in addition to code for primary procedure) [auriculotemporal nerve block]

+61800
Application of stereotactic headframe for stereotactic radiosurgery (List separately in addition to code for primary procedure) [auriculotemporal nerve block]

61850
Twist drill or burr hole(s) for implantation of neurostimulator electrodes, cortical

61860
Craniectomy or craniotomy for implantation of neurostimulator electrodes, cerebral, cortical

61863
Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g. thalamus, globus pallidus, subthalamus nucleus, periventricular, periaqueductal gray, without use of intraoperative microelectrode recording; first array
+61864 each additional array (List separately in addition to primary procedure)

61867 Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g. thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray, with use of intraoperative microelectrode recording; first array

+61868 each additional array (List separately in addition to primary procedure)

61870 Cranietomy for implantation of neurostimulator electrodes, cerebellar; cortical

61875 subcortical

61880 Revision or removal of intracranial neurostimulator electrode

61885 Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array

61886 Incision and subcutaneous placement of cranial neurostimulator pulsed generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays

61888 Revision or removal of cranial neurostimulator pulse generator or receiver

62280 Injection/infusion of neurolytic substance, with or without other therapeutic substance; subarachnoid

62281 Injection/infusion of neurolytic substance, with or without other therapeutic substance; epidural, cervical or thoracic

63020 Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; one interspace, cervical

+ 63035 each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)

63040 Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical

+ 63043 each additional cervical interspace (List separately in addition to code for primary procedure)
63045  Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root(s), (e.g., spinal or lateral recess stenosis)), single vertebral segment; cervical

+ 63048  each additional segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)

63050  Laminoplasty, cervical, with decompression of the spinal cord, two or more vertebral segments

63075  Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, single interspace

+ 63076  cervical, each additional interspace (List separately in addition to code for primary procedure)

63077  thoracic, single interspace

63081  Vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve root(s); cervical, single segment

+ 63082  cervical, each additional segment (List separately in addition to code for primary procedure)

64400  Injection, anesthetic agent; trigeminal nerve, any division or branch

64402  facial nerve

64405  greater occipital nerve

64408  vagus nerve

64410  phrenic nerve

64412  spinal accessory nerve

64413  cervical plexus

64418  suprascapular nerve

64550  Application of surface (transcutaneous) neurostimulator

64553  Percutaneous implantation of neurostimulator electrode array; cranial nerve

64555  Percutaneous implantation of neurostimulator electrode array; peripheral nerve(excludes sacral nerve)

64565  Percutaneous implantation of neurostimulator electrode array; neuromuscular
64575  peripheral nerve (excludes sacral nerve)
64580  Incision for implantation of neurostimulator electrode array; neuromuscular
64585  Revision or removal of peripheral neurostimulator electrode array
64590  Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64600  Destruction by neurolytic agent, trigeminal nerve; supraorbital, infraorbital, mental, or inferior alveolar branch
64612  Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)
64616  neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)
64633  Destruction by neurolytic agent, paravertebral facet joint nerve(s) with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634  cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure)
64702 - 64727  Neuroplasty digital, or major peripheral nerve, arm or leg, open, or neuroplasty and/or transposition, or decompression, unspecified nerve, or internal neurolysis, requiring use of operating microscope
77371  Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based
77372  linear accelerator based
77432  Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of one session)
95970  Electronic analysis of implanted neurostimulator pulse generator system (e.g. rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95971  simple brain, spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse
generator/transmitter, with intraoperative or subsequent programming

95972   complex brain, spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour

95973   complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)

95974   complex cranial nerve neurostimulator, pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour

+95975   complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)

95978   Electronic analysis of implanted neurostimulator pulse generator system (e.g. rate, pulse amplitude and duration, battery status, electrode selectability, and polarity, impedance and patient compliance measurements); complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming, first hour

+95979   each additional 30 minutes after first hour (List separately in addition to code for primary procedure)

97014   Application of a modality to 1 or more areas; electrical stimulation (unattended)

**HCPCS codes not covered for indications listed in the CPB:**

A4556   Electrodes (e.g., apnea monitor), per pair

A4557   Lead wires (e.g., apnea monitor), per pair

A4558   Conductive gel or paste, for use with electrical device (e.g., TENS, NMES)

A4595   Electrical stimulator supplies, 2 lead, per month (e.g., TENS, NMES)

C1767   Generator, neurostimulator (implantable), nonrechargeable

C1778   Lead, neurostimulator (implantable)

C1816   Receiver and/or transmitter, neurostimulator (implantable)
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1883</td>
<td>Adaptor/extension, pacing lead or neurostimulator lead (implantable)</td>
</tr>
<tr>
<td>C1897</td>
<td>Lead, neurostimulator test kit (implantable)</td>
</tr>
<tr>
<td>E0720</td>
<td>Transcutaneous electrical nerve stimulation (TENS) device, 2 lead, localized stimulation</td>
</tr>
<tr>
<td>E0730</td>
<td>Transcutaneous electrical nerve stimulation (TENS) device, 4 or more leads for multiple nerve stimulation</td>
</tr>
<tr>
<td>E0731</td>
<td>Form-fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric)</td>
</tr>
<tr>
<td>E0745</td>
<td>Neuromuscular stimulator, electronic shock unit</td>
</tr>
<tr>
<td>G0173</td>
<td>Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session</td>
</tr>
<tr>
<td>G0251</td>
<td>Linear accelerator based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, maximum five sessions per course of treatment</td>
</tr>
<tr>
<td>G0339</td>
<td>Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment</td>
</tr>
<tr>
<td>G0340</td>
<td>Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment</td>
</tr>
<tr>
<td>J0585</td>
<td>Botulinum toxin type A, per unit</td>
</tr>
<tr>
<td>J0586</td>
<td>Botulinum toxin type B, per 100 units</td>
</tr>
<tr>
<td>J0587</td>
<td>Injection, Incobotulinumtoxin A, 1 unit</td>
</tr>
<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
</tr>
<tr>
<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only</td>
</tr>
<tr>
<td>L8682</td>
<td>Implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8683</td>
<td>Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
</tr>
</tbody>
</table>
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, replacement only

L8695  External recharging system for battery (external) for use with implantable neurostimulator, replacement only

ICD-9 codes not covered for indications listed in the CPB:

307.81  Tension headache

339.00 - 339.89  Other headache syndromes

346.00 - 346.93  Migraine

784.0  Headache

Other ICD-9 codes related to the CPB:

353.2  Cervical root lesions, not elsewhere classified

722.0  Displacement of cervical intervertebral disc without myelopathy

722.81  Postlaminectomy syndrome, cervical region

The above policy is based on the following references:


63. Garza I. Occipital neuralgia. Last reviewed June 2012. UpToDate Inc. Waltham, MA.
64. Biondi DM, Bajwa ZH. Cervicogenic headache. Last reviewed June 2012. UpToDate Inc. Waltham, MA.
65. Garza I, Schwedt TJ. Overview of chronic daily headache. Last reviewed June 2012. UpToDate Inc. Waltham, MA.
73. Garza I, Schwedt TJ. Chronic migraine. UpToDate Inc., Waltham, MA. Last reviewed June 2014.