

OCCIPITAL NEURALGIA AND HEADACHE TREATMENT

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INSTRUCTIONS FOR USE

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COVERAGE RATIONALE

Injection of local anesthetics and/or steroids, used as occipital nerve blocks, is proven and medically necessary for the treatment of pain due to malignancy involving the head and neck.

Injection of local anesthetics and/or steroids, used as occipital nerve blocks, is unproven and not medically necessary for the diagnosis and treatment of occipital neuralgia or headaches including migraine and cervicogenic headaches.

There is insufficient evidence that greater occipital nerve blocks can be used as a specific diagnostic test for occipital neuralgia or headaches. The efficacy of local injection therapies for occipital neuralgia or cervicogenic headache and other headaches has not been established in well-designed clinical trials.

See the Drug Policy titled [Botulinum Toxin A and B](#) for information regarding the use of botulinum toxin for treatment of headaches.

Surgery including but not limited to the following is unproven and not medically necessary for the treatment of occipital neuralgia or cervicogenic headache:

- Occipital neurectomy
- Partial posterior intradural C1-C3 rhizotomy
- Rhizotomy of C1-C3 spinal dorsal roots
- Surgical decompression of second cervical nerve root and ganglion
- Surgical decompression of the greater occipital nerve

The available evidence is insufficient to conclude that surgery is an effective treatment for occipital neuralgia or cervicogenic-headaches. The long-term efficacy of surgical procedures for occipital neuralgia or cervicogenic headaches has not been established in well-designed clinical trials.

Occipital neurectomy or surgical nerve decompression is unproven and not medically necessary for the treatment of headaches.

The available evidence is insufficient to conclude that occipital neurectomy or nerve decompression including decompression of the supraorbital, supratrochlear, zygomaticotemporal, or greater occipital nerves is an effective treatment for headaches. The long-term efficacy of these procedures for headaches has not been established in well-designed clinical trials.

Radiofrequency ablation (thermal or pulsed) or denervation is unproven and not medically necessary for the treatment of occipital neuralgia or headaches including migraine, cluster and cervicogenic headache.

The available evidence from published studies is not sufficient to conclude that radiofrequency ablation or denervation is an effective treatment for occipital neuralgia or headaches. Well-designed studies are needed to evaluate the potential advantages of radiofrequency ablation for these conditions and to identify which patients would benefit from this procedure.

Neurostimulation or electrical stimulation is unproven and not medically necessary for the treatment of occipital neuralgia or headaches including migraine, cluster and cervicogenic headache.

The available studies were limited and had significant methodological flaws, making it difficult to draw conclusions regarding the efficacy of electrical stimulation for the treatment of headache or occipital neuralgia. There are no well-designed randomized controlled studies in the medical literature comparing neurostimulation to established treatment options or a sham procedure. Studies on larger populations with longer follow-up are needed to establish the benefits of neurostimulation and electrical stimulation for treating these conditions.

APPLICABLE CODES

The Current Procedural Terminology (CPT[®]) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

| CPT [®] Code | Description |
|-----------------------|--|
| 62281 | Injection/infusion of neurolytic substance (eg, alcohol, phenol, iced saline solutions), with or without other therapeutic substance; epidural, cervical or thoracic |
| 63185 | Laminectomy with rhizotomy; 1 or 2 segments |

| CPT[®] Code | Description |
|-----------------------------|---|
| 63190 | Laminectomy with rhizotomy; more than 2 segments |
| 64405 | Injection, anesthetic agent; greater occipital nerve |
| 64553 | Percutaneous implantation of neurostimulator electrodes; cranial nerve |
| 64555 | Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve) |
| 64568 | Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator |
| 64570 | Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator |
| 64575 | Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve) |
| 64590 | Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling |
| 64633 | Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint |
| 64634 | Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure) |
| 64722 | Decompression; unspecified nerve(s) (specify) |
| 64744 | Transection or avulsion of; greater occipital nerve |
| 64771 | Transection or avulsion of other cranial nerve, extradural |
| 64999 | Unlisted procedure, nervous system |
| 95972 | Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour |
| 0282T | Percutaneous or open implantation of neurostimulator electrode array(s), subcutaneous (peripheral subcutaneous field stimulation), including imaging guidance, when performed, cervical, thoracic or lumbar; for trial, including removal at the conclusion of trial period |
| 0283T | Percutaneous or open implantation of neurostimulator electrode array(s), subcutaneous (peripheral subcutaneous field stimulation), including imaging guidance, when performed, cervical, thoracic or lumbar; permanent, with implantation of a pulse generator |
| 0284T | Revision or removal of pulse generator or electrodes, including imaging guidance, when performed, including addition of new electrodes, when performed |
| 0285T | Electronic analysis of implanted peripheral subcutaneous field stimulation pulse generator, with reprogramming when performed |

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| HCPCS Code | Description |
|-------------------|--|
| E0720 | Transcutaneous electrical nerve stimulation (TENS) device, two lead, localized stimulation |
| L8679 | Implantable neurostimulator, pulse generator, any type |
| L8680 | Implantable neurostimulator electrode (with any number of contact points), each |

| HCPSC Code | Description |
|------------|--|
| L8683 | Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver |
| L8685 | Implantable neurostimulator pulse generator, single array, rechargeable, includes extension |

| ICD-9 Diagnosis Code | Description |
|----------------------|---|
| 338.3 | Neoplasm related pain (acute) (chronic) |

ICD-10 Codes (Preview Draft)

In preparation for the transition from ICD-9 to ICD-10 medical coding on **October 1, 2015***, a sample listing of the ICD-10 CM and/or ICD-10 PCS codes associated with this policy has been provided below for your reference. This list of codes may not be all inclusive and will be updated to reflect any applicable revisions to the ICD-10 code set and/or clinical guidelines outlined in this policy. **The effective date for ICD-10 code set implementation is subject to change.*

| ICD-10 Diagnosis Code (Effective 10/01/15) | Description |
|--|---|
| G89.3 | Neoplasm related pain (acute) (chronic) |

DESCRIPTION OF SERVICES

Cervicogenic headache and occipital neuralgia are conditions whose diagnosis and treatment have been gradually refined over the last several years. This terminology has come to refer to specific types of unilateral headache thought to arise from impingement or entrapment of the occipital nerves and/or the upper spinal vertebrae. Compression and injury of the occipital nerves within the muscles of the neck and compression of the second and third cervical nerve roots are generally felt to be responsible for the symptoms, including unilateral and occasionally bilateral head, neck, and arm pain. The criteria for diagnosis of these entities currently include those of the International Headache Society (IHS) and the Cervicogenic Headache International Study Group.

Various treatments have been advocated for cervicogenic headache and occipital neuralgia. Oral analgesics and anti-inflammatory agents are effective for some patients, but there is a population of patients who do not experience pain relief with these medications. Local injections or nerve blocks, epidural steroid injections, radiofrequency ablation of the planum nuchae, electrical stimulation, rhizotomy, ganglionectomy, nerve root decompression, discectomy and spinal fusion have all been investigated in the treatment of headache and occipital neuralgia.

Since medications provide only temporary relief and may cause side effects, surgical treatments such as occipital neurectomy and nerve decompression for migraine and other headaches have been developed as a potential means to permanently prevent or to produce long-term remissions from headaches.

Radiofrequency ablation is performed percutaneously. During the procedure, an electrode that generates heat produced by radio waves is used to create a lesion in a sensory nerve with the intent of inhibiting transmission of pain signal from the sensory nerve to the brain.

Neurostimulation or electrical stimulation is commonly used for control of chronic pain. Electrical stimulation can be delivered in 3 ways: transcutaneously, percutaneously, and using implantable devices. Peripherally implanted nerve stimulation entails the placement of electrodes on or near a selected peripheral nerve. Targets for stimulation include occipital nerves, auriculotemporal nerves, supraorbital nerves, and sphenopalatine ganglia.

CLINICAL EVIDENCE

Diagnostic Occipital Nerve Blocks

Greater occipital nerve blocks have been advocated as a diagnostic test for cervicogenic headache and occipital neuralgia. However, criteria and standards for diagnostic occipital nerve blocks remain to be defined. There are no well-designed clinical trials that clearly indicate that injection of the greater occipital nerve can be used as a specific diagnostic test for headaches and occipital neuralgia.

The diagnostic value of greater occipital and supra-orbital nerve blockades in patients with cervicogenic headache (n=24), migraine without aura (n=14), and tension-type headache (n=14) was investigated. The pain reduction after greater occipital nerve blockade was significantly more marked in the cervicogenic headache group than in the other categories. Moreover, pain reduction in the forehead was generally only found in the cervicogenic headache patients (77%). Pain reduction was significantly more marked following the greater occipital than the supra-orbital nerve blockade. The volume effect per se was evaluated by saline injection. This procedure did not result in distinct pain reduction. The effect obtained in cervicogenic headache is, accordingly, probably due to the local anaesthesia. The present results support the postulate that different pathogenetic factors probably are responsible for cervicogenic headache, tension-type headache, and migraine without aura (Bovim and Sand 1992). These findings require confirmation in a larger study.

According to the International Headache Society, the diagnostic criteria for cervicogenic headache include the following (International Headache Society, 2005):

- Pain, referred from a source in the neck and perceived in one or more regions of the head and/or face, fulfilling criteria C and D
- Clinical, laboratory and/or imaging evidence of a disorder or lesion within the cervical spine or soft tissues of the neck known to be, or generally accepted as, a valid cause of headache
- Evidence that the pain can be attributed to the neck disorder or lesion based on at least one of the following:
 - demonstration of clinical signs that implicate a source of pain in the neck
 - abolition of headache following diagnostic blockade of a cervical structure or its nerve supply using placebo or other adequate controls
- Pain resolves within 3 months after successful treatment of the causative disorder or lesion.

According to the International Headache Society, the diagnostic criteria for occipital neuralgia include the following (International Headache Society, 2005):

- Paroxysmal stabbing pain, with or without persistent aching between paroxysms, in the distribution(s) of the greater, lesser and/or third occipital nerves
- Tenderness over the affected nerve
- Pain is eased temporarily by local anaesthetic block of the nerve

Therapeutic Occipital Nerve Blocks

Cervicogenic Headache

Gabrhelik et al. (2011) compared the efficacy of pulsed radiofrequency to the greater occipital nerve versus a greater occipital nerve block with a mixture of local anaesthetic and steroid in the management of refractory cervicogenic headache. The study included 30 patients who were randomly allocated into two groups of fifteen. A greater occipital nerve block with steroid was utilized in group A, while a pulsed radiofrequency treatment was used in group B. At three months post therapy a significant decrease in Visual Analogue Scale was identified (3.2 points in group A, 3.3 points in group B). In group B, pain remained reduced even after 9 months when compared to pre-treatment scores. The consumption of analgesic medication was reduced significantly in both

groups at three months and nine months. No serious complication was noted. The authors concluded that greater occipital nerve block is a safe, efficient technique in the management of cervicogenic headaches. According to the authors, the main limitation of this study is a small sample size.

In a randomized, double-blind, placebo-controlled trial, Naja et al. (2006a) evaluated the effectiveness of nerve stimulator-guided occipital nerve blockade in the treatment of cervicogenic headache. The reduction in analgesic consumption was the primary outcome measure. Fifty adult patients diagnosed with cervicogenic headache were randomly divided into two equal groups of 25 patients each. All patients in both groups received greater and lesser occipital blocks, whereas only 16 patients in each group received facial nerve blockade in association with the occipital blocks. The control group received injections of an equivalent volume of preservative-free normal saline. Pain was assessed using the visual analog scale (VAS) and the Total Pain Index (TPI). Forty-seven patients entered into the final analysis as three patients were lost to follow-up. Anesthetic block was effective in reducing the VAS and the TPI by approximately 50% from baseline values. Analgesic consumption, duration of headache and its frequency, nausea, vomiting, photophobia, phonophobia, decreased appetite, and limitations in functional activities were significantly less in block group compared to control group. The nerve stimulator-guided occipital nerve blockade significantly relieved cervicogenic headache and associated symptoms at two weeks following injection. This study is limited by a small sample size. Another major limitation of the study is the short duration of follow-up. The patients included in the study were followed for 2 weeks, so long-term outcome was not evaluated. The difficulty in blinding when numbness resulted in patients who received anesthetic blockade is another limitation of this study. In a follow-up trial, the same group evaluated 47 patients with cervicogenic headaches and found that 87% of the patients required more than one occipital nerve injection to achieve 6 months of pain relief (Naja, 2006).

Gale et al. (2002) conducted a six week randomized study to compare the efficacy of nerve blocks and cognitive therapy for treating cervicogenic headaches. The study included a consecutive series of 68 patients who were already receiving nerve block therapy. Patients attended eight weekly treatment sessions. Baseline and seven weekly sets of values were recorded. The principal measure of outcome was the Pain on a Visual Analogue Scale (VAS). Within the first week, one patient of 34 in the nerve block group withdrew and 12 of 34 in the cognitive therapy group withdrew from the study. After seven weeks, 33 patients in the nerve block group remained in the trial, but only 21 patients completed the questionnaires. Four of 22 patients in the cognitive therapy group completed the trial and their questionnaires. Mean VAS scores in the nerve block group dropped slightly during treatment. According to the authors, there were no statistically significant differences between the two treatment modalities in antinociceptive efficacy for those participants who remained in the study. This study was limited by a lack of treatment concealment and the large number of drop outs in the study.

Inan et al. (2001) compared the greater occipital nerve (GON) and C2/C3 nerve blocks in the diagnosis and treatment of cervicogenic headache in 28 patients. In both cases, repeated blocks proved to have a long-lasting effect in the treatment of this disorder, with both GON and C2/C3 blocks being found to be equally effective. This study is limited by a small sample size.

In a prospective case series, injections of depot methylprednisolone into the region of the GON and lesser occipital nerve (LON) produced complete relief of cervicogenic headache in 169 out of 180 patients for a period ranging from 10 to 77 days, the mean duration of relief being 23.5 days. This study is nonrandomized and uncontrolled, limiting the validity of its conclusions (Anthony, 2000).

In a prospective non-controlled trial, Vincent et al. (1998) studied the effect of GON blocks using 0.5% bupivacaine in 41 patients with cervicogenic headache. The investigators found a significant reduction in head pain at 1 week post injection, as compared with pain during the week before injection. This study is limited by a small sample size and the lack of a comparison group.

Martelletti et al. (1998) compared the results of 9 patients with cervicogenic headaches who received epidural steroid injections and 6 patients with chronic tension headaches who received the same procedure. A decrease in the Numeric Intensity Scale and the Drug Consumption Index were observed in the cervicogenic headache patients.

Weibelt et al. (2010) evaluated the safety and efficacy of occipital nerve blocks (ONBs) used to treat cervicogenic chronic migraine (CCM) and identified variables predictive of a positive treatment response. A positive treatment outcome was defined as a 50% or greater reduction in headache days per month over the 30 days following treatment relative to the 30-day pre-treatment baseline. A total of 150 consecutive patients were treated with unilateral (37) or bilateral (113) ONBs. At the 1-month follow-up visit, 78 (52%) exhibited evidence of a positive treatment response according to the primary outcome variable, and 90 (60%) reported their headache disorder to be "better" (44; 29%) or "much better" (46; 30%). A total of 8 (5%) patients reported adverse events within the ensuing 72 hours, and 3 (2%) experienced adverse events that reversed spontaneously but required emergent evaluation and management. The investigators concluded that for suppression of CCM, ONBs may offer an attractive alternative to orally administered prophylactic therapy. This study lacked a control group and the data used for analyzing the primary outcome variable were partially dependent on patient recall. Both recall bias and placebo effect could have inflated the response rate.

Na et al. (2010) evaluated the efficacy of ultrasonic Doppler flowmeter-guided occipital nerve block in 26 patients experiencing headache in the occipital region in a randomized, prospective, placebo-controlled study. Patients received a greater occipital nerve block performed either under ultrasonic Doppler flowmeter guidance using 1% lidocaine or the traditional method. Sensory examination findings in the occipital region were evaluated. The complete block rate of greater occipital nerve blockade in the Doppler group was significantly higher than in the control group respectively (76.9% vs. 30.8%). Only one patient in the control group had a complication (minimal bleeding). The authors concluded that ultrasonic Doppler flowmeter-guided occipital nerve block may be a useful method for patients suffering headache in the occipital region. These findings require confirmation in a larger study.

The 2011 Hayes Directory on local injection therapy and neurosurgery for cervicogenic headache and occipital neuralgia states that injection therapies using anesthetic agents may provide effective pain relief for some patients. However, the available studies were limited and many had significant methodological flaws, making it difficult to draw strong conclusions. In addition, most results suggest that pain relief was temporary and a substantial proportion of patients experienced recurrences (Hayes, 2011).

Other Headaches

Ashkenazi et al. (2010) performed a systematic review of peripheral nerve blocks (PNBs) and trigger point injections (TPIs) for headache treatment. The authors found few controlled studies on the efficacy of PNBs for headaches, and virtually none on the use of TPIs for headaches. The most widely examined procedure in this setting was greater occipital nerve block, with the majority of studies being small and non-controlled. The techniques, as well as the type and doses of local anesthetics used for nerve blockade, varied greatly among studies. The specific conditions treated also varied, and included both primary (e.g., migraine, cluster headache) and secondary (e.g., cervicogenic, posttraumatic) headache disorders. According to the authors, results for PNBs were generally positive, but should be taken with reservation given the methodological limitations of the available studies. These limitations included small patient populations, retrospective, non-controlled designs, and heterogeneous groups of patients. The authors concluded that there is a need to perform more rigorous clinical trials to clarify the role of PNBs and TPIs in the management of various headache disorders, and to aim at standardizing the techniques used for the various procedures in this setting.

Leroux et al. (2011) conducted a randomized, double-blind, placebo-controlled trial that included adults with more than two cluster headache attacks per day. Forty-three patients were randomly allocated to receive three suboccipital injections (48-72 hours apart) of cortivazol or placebo, as add-on treatment to oral verapamil in patients with episodic cluster headache and as add-on prophylaxis for those with chronic cluster headache. Injections were done by physicians who were aware of treatment allocation, but patients and the evaluating physician were masked to allocation. Twenty of 21 patients who received cortivazol had a mean of two or fewer daily attacks after injections compared with 12 of 22 controls. Patients who received cortivazol also had fewer attacks in the first 15 days of study than did controls. No serious adverse events were noted. Thirty-two (74%) of 43 patients had other adverse events (18 of 21 patients who received cortivazol and 14 of 22 controls). The most common adverse events were injection-site neck pain and non-cluster headache. According to the authors, suboccipital cortivazol injections can relieve cluster headaches rapidly in patients having frequent daily attacks, irrespective of type (chronic or episodic). The authors stated that safety and tolerability need to be confirmed in larger studies.

In a double-blind placebo-controlled trial, Ambrosini et al. (2005) assessed the preventive effect of an ipsilateral steroid injection in the region of the greater occipital nerve on cluster headache (CH). Sixteen episodic (ECH) and seven chronic (CCH) CH outpatients were included. After a one-week run-in period, patients were allocated by randomization to the placebo or verum acupuncture arms and received on the side of attacks a suboccipital injection of a mixture of long- and rapid-acting betamethasone (n=13; verum-group) or physiological saline (n=10; placebo-group). Acute treatment was allowed at any time, additional preventative therapy if attacks persisted after 1 week. Three investigators performed the injections, while four others, blinded to group allocation, followed the patients. Follow-up visits were after 1 and 4 weeks, where after patients were followed routinely. Eleven verum-group patients (3 CCH) (85%) became attack-free in the first week after the injection compared to none in the placebo-group. Among them eight remained attack-free for 4 weeks. Remission lasted between 4 and 26 months in five patients. According to the investigators, a single suboccipital steroid injection completely suppressed attacks in more than 80% of CH patients. A limitation of this study is small sample size.

Lambru et al. (2013) prospectively assessed the efficacy and consistency of response to greater occipital nerve blockade (GONB) in a series of 83 chronic cluster headache (CCH) patients. After the first GONB, a positive response was observed in 47 (57%) patients: 35 (42%) were rendered pain free, 12 (15%) had a partial benefit and one patient obtained <50% improvement. The duration of a positive response lasted a median of 21 days (range 7-504 days). There was a transient worsening of condition in 6% of patients. The overall rate and average duration of response remained consistent after the second [n = 37; 31 responders (84%); median duration 21 days], third [n = 28; 20 responders (71%); median duration 25 days] and fourth [n = 14; 10 responders (71%); median duration 23 days] injections. The authors concluded that GONB seems to be an efficacious treatment with reproducible effects in CCH patients. According to the authors, when performed three times monthly, GONB may have a useful role in the management of CCH. The lack of a control group limits the validity of the results of this study.

Grantenbein et al. (2012) retrospectively analyzed the efficacy and safety of 121 GON injections in 60 patients with episodic or chronic cluster headache over a period of 4 years. Almost 80% of the infiltrations were at least partially effective (reduction of attack frequency, duration or severity) and 45% resulted in a complete response (no further attacks). The effect was maintained for 3.5 weeks on average in chronic cluster headache. In episodic cluster headache, the effect lasted for most of the bout. In 18 infiltrations, transient side effects were reported, such as local pain, steroid effects (facial oedema, sleeping disorders, acne), bradycardia or syncope. The authors concluded that GON infiltration is a valuable and safe option in the clinical setting to treat patients suffering from cluster headache, especially for the episodic form of the disorder. This is an uncontrolled study with a small sample size.

Busch et al. (2007) evaluated the clinical outcome in 15 chronic cluster headache patients before and after unilateral nerve blockade of the greater occipital nerve with 5 ml prilocain (1%) on the

headache side. Nine of the 15 cluster patients reported some minor improvement in their headache. Six patients did not report any clinical change. Peres et al. (2002) treated 14 cluster headache patients with greater occipital nerve block as transitional therapy (treatment initiated at the same time as preventive therapy). The mean number of headache-free days was 13.1 + 23.6. Four patients (28.5%) had a good response, five (35.7%) a moderate, and five (35.7%) no response. Headache intensity, frequency and duration were significantly decreased comparing the week before with the week after the nerve block. These studies are limited by small sample size and lack of control groups.

In a randomized controlled study, Ashkenazi et al. (2008) examined the effect of greater occipital nerve block (GONB) and trigger-point injections (TPIs) on headache in patients with transformed migraine (TM). Thirty-seven patients with TM were randomized to receive GONB and TPIs using lidocaine 2% and bupivacaine 0.5% plus either saline or triamcinolone 40 mg. Twenty minutes after injection, there was a significant decrease in the severity of headache and associated symptoms in both groups, with no significant between-group difference in the majority of outcome measures (the exception was the decrease in phonophobia that was more pronounced in the group that received triamcinolone with the local anesthetics). These findings require confirmation in a larger study.

Saracco et al. (2010) assessed whether adding triamcinolone to local anaesthetics increased the efficacy of greater occipital nerve block (GONB) and trigger point injections (TPIs) for chronic migraine. Thirty-seven patients with chronic migraine were randomized to receive GONB and TPIs using lidocaine 2% and bupivacaine 0.5% plus either saline (group A) or triamcinolone 40 mg (group B). Patients documented headache and severity of associated symptoms for 4 weeks after injection. Changes in symptom severity were compared between the two groups. Twenty minutes after injection, mean headache severity decreased by 3.2 points in group A and by 3.1 points in group B. Mean neck pain severity decreased by 1.5 points in group A and by 1.7 points in group B. Mean duration of being headache-free was 2.7 +/- 3.8 days in group A and 1.0 +/- 1.1 days in group B. None of the outcome measures differed significantly between the two groups. According to the investigators, adding triamcinolone to local anaesthetic when performing GONB and TPIs was not associated with improved outcome in the sample of patients with chronic migraine. In both groups, the procedure resulted in significant and rapid relief of headache, neck pain, and photophobia. The study is limited by a small sample size and lack of a control therapy.

Afridi et al. (2006) found that 26 of 57 greater occipital nerve injections in 54 migraineurs yielded a complete or partial response that lasted for the partial response a median of 30 days. For cluster headache 13 of 22 injections yielded a complete or partial response lasting for a median of 21 days for the partial response. Tenderness over the GON was strongly predictive of outcome, although local anesthesia after the injection was not. The presence or absence of medication overuse did not predict outcome. The investigators concluded that GON injection is a useful tool in some patients that provides interim relief while other approaches are explored. The lack of a control group limits the validity of the results of this study.

Naja et al. (2009) conducted a prospective, randomized, single-blinded comparison between bilateral occipital blockade and conventional expectant therapy in adults suffering from postdural puncture headache (PDPH). Fifty adult patients diagnosed with PDPH were randomly divided into two equal groups of 25 each. All patients in the block group received greater and lesser occipital nerve blocks, whereas the control group received adequate hydration, complete bed rest, and analgesics. Forty-seven patients entered into the final analysis as three patients withdrew from study. Complete pain relief was achieved in 68.4% of block patients after 1 to 2 blocks, with 31.6% ultimately receiving up to 4 blocks. Visual analog scales were significantly lower in the block group, and the block group consumed significantly less analgesics in the follow-up period compared with control group. Block patients had significantly shorter hospital stays and sick leave periods. The investigators concluded that occipital nerve blockade is superior to expectant conservative therapy in the treatment of patients suffering from PDPH. These findings require confirmation in a larger study.

Tobin et al. (2009) conducted a chart review of 108 occipital nerve blocks (ONBs) to explore the effect of symptomatic medication overuse (SMO) and ONB efficacy. ONB failed in 22% of injections overall. Of the other 78%, the mean decrease in head pain was 83%, and the benefit lasted a mean of 6.6 weeks. Failure rate without SMO was 16% overall, and with SMO was 44% overall. In those who did respond, overall magnitude and duration of response did not differ between those with and those without SMO. Without SMO, ONB failure rate was 0% for postconcussive syndrome, 14% for occipital neuralgia, 11% for non-intractable migraine, and 39% for intractable migraine. With SMO, failure rate increased by 24% in occipital neuralgia, by 36% for all migraine, and by 52% for non-intractable migraine. The investigators concluded that SMO tripled the risk of ONB failure, possibly because medication overuse headache does not respond to ONB. This study lacked a control group.

In an open pilot study, Leinisch-Dahlke et al. (2005) investigated the effect of bilateral block of the greater occipital nerve with 50 mg prilocaine and 4 mg dexamethasone in patients with chronic tension type headache. From 15 patients, only one patient described a headache relief after initial exacerbation of headache for 2 days. Headache intensity was unchanged in 11 patients. In three patients, the headache worsened in the first hours or days after injection. The investigators concluded that a block of the greater occipital nerve is not effective in the treatment of chronic tension type headache.

Other studies have been performed that indicate that greater occipital nerve blocks may be an effective treatment for patients with migraine postconcussive, or other headaches; however, these studies had small sample sizes or did not have control groups (Guerrero, 2012; Young, 2008; Akin, 2008; Caputi, 1997; Hecht, 2004; Ashkenazi, 2005; Saadah and Taylor, 1987).

The American Headache Society Special Interest Section for peripheral nerve blocks (PNBs) and other Interventional Procedures (AHS-IPS) developed a narrative review describing a standardized methodology for the performance of PNBs in the treatment of headache disorders. PNBs described included greater occipital, lesser occipital, supratrochlear, supraorbital, and auriculotemporal injections. The indications for PNB may include select primary headache disorders, secondary headache disorders, and cranial neuralgias. According to the authors, there is a paucity of evidence from controlled studies for the use of PNBs in the treatment of primary and secondary headache disorders, with the exception of greater occipital nerve blockade for cluster headaches. The AHS-IPS indicated that further research may result in the revision of these recommendations to improve the outcome and safety of this treatment modality for headache (Blumenfeld et al. 2013).

The National Comprehensive Cancer Network (NCCN) practice guidelines (2013) for Adult Cancer Pain indicates that head and neck peripheral nerve blocks are commonly used as interventional procedures for well-localized cancer pain syndromes. This recommendation is based on category 2A level of evidence (lower-level evidence and NCCN consensus).

Surgical Treatment of Occipital Neuralgia or Cervicogenic Headache

A number of different surgical procedures such as dorsal nerve root section, occipital neurectomy, partial posterior rhizotomy, cervical spine disc excision with fusion, and surgical nerve release have been studied for the treatment of occipital neuralgia and cervicogenic headache. However, the available evidence comes primarily from small retrospective case series studies and is insufficient to conclude that surgery is an effective treatment for occipital neuralgia or cervicogenic headache.

Excision of intervertebral discs from the cervical spine with interbody fusion was evaluated in two prospective case series by the same authors. In patients with bilateral cervicogenic headache (n=28), 64% reported relief of pain after surgery, and the mean duration of improvement was 22.7 months. In 36% of patients, immediate pain reduction was followed by recurrences starting at 2 months after surgery (Jansen and Sjaastad, 2006). In patients with unilateral cervicogenic

headache, these same authors reported that all patients were generally pain free during the 1- to 3-month period when the patients wore cervical collars restricting movement, but only 5 out of 32 patients remained pain free 3 years after surgery. The mean duration of improvement was 14.8 months (range, 1 to 58 months) (Jansen and Sjaastad, 2007). In another study, Jansen (2008) summarized the results of cervical disc removal in 60 patients with long lasting severe unilateral (n = 32) or bilateral (n = 28) cervicogenic headache unresponsive to other treatment options. Sixty-three per cent of the unilateral and 64% of the bilateral cases had long lasting pain freedom or improvement. After secondary deterioration (in 37% of patients with unilateral and in 36% with bilateral CEH) and further treatments, the final mean improvement was 73% and 66%, respectively. The mean observation time was short (19.8 to 25.5 months). These conclusions are limited by the small sample size in the reported studies.

In a prospective study, Diener et al. (2007) investigated whether cervical disc prolapse can cause cervicogenic headache. The study included 50 patients with cervical disc prolapse who were prospectively followed for 3 months. Data regarding headache and neck pain were collected prior to and 7 and 90 days after surgery for the disc prolapse. Fifty patients with lumbar disc prolapse, matched for age and sex, undergoing surgery were recruited as controls. Twelve of 50 patients with cervical disc prolapse reported new headache and neck pain. Seven patients (58%) fulfilled the 2004 International Headache Society criteria for cervicogenic headache. One week after surgery, 8/12 patients with cervical disc prolapse and headache reported to be pain free. One patient was improved and three were unchanged. Three months after cervical prolapse surgery, seven patients were pain free, three improved and two unchanged. According to the authors, this prospective study shows an association of low cervical prolapse with cervicogenic headache: headache and neck pain improves or disappears in 80% of patients after surgery for the cervical disc prolapse. These findings require confirmation in a larger study.

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. Of 206 patients, 190 underwent greater occipital nerve neurolysis (171 bilateral). Twelve patients underwent greater and lesser occipital nerve excision, whereas four underwent lesser occipital nerve excision alone. The investigators found that 80.5% of patients experienced at least 50% pain relief and 43.4% of patients experienced complete relief of headache. Minimum duration of follow-up was 12 months (Ducic et al., 2009). Interpretation of these findings is limited due to the retrospective design of the study.

In a retrospective review, Pisapia et al. (2012) evaluated the effectiveness of C2 nerve root decompression and C2 dorsal root ganglionectomy for intractable occipital neuralgia (ON) and C2 ganglionectomy after pain recurrence following initial decompression. Of 43 patients, 29 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). Telephone contact supplemented chart review and patients rated their preoperative and postoperative pain on a 10-point numeric scale. 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 5.6 years), patients undergoing decompression, ganglionectomy, or decompression followed by ganglionectomy experienced similar outcomes, with mean pain reduction ratings of 5, 4.5, and 5.7, respectively. Of 19 telephone responders, 13 (68%) rated overall operative results as very good or satisfactory. According to the authors, most patients experienced favorable postoperative pain relief. The authors stated that 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. The moderate rate of follow-up (67%) may have skewed the results of this study.

In a retrospective chart review, Acar et al. (2008) evaluated 20 patients who underwent C2 and/or C3 ganglionectomies for intractable occipital pain. All patients reported preoperative pain relief following cervical nerve blocks. The mean follow-up was 42.5 months. Average visual analog scale scores were 9.4 preoperatively and 2.6 immediately after procedure. Ninety-five percent of

patients reported short-term pain relief (<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. The investigators concluded that 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 cannot justify surgery by itself.

Li et al. (2102) evaluated the clinical effect of micro-surgical decompression of the greater occipital nerve for greater occipital neuralgia (GON) in 76 patients. The mean follow up duration was 20 months (range 7-52 months). The headache symptoms of 68 patients (89.5%) were completely resolved, and another 5 patients (6.6%) were significantly relieved without the need for any further medical treatment. Three patients (3.9%) experienced recurrence of the disorder. All patients experienced hypoesthesia of the innervated area of the great occipital nerve. They recovered gradually within 1 to 6 months after surgery. According to the authors, micro-surgical decompression is a promising therapy for GON given its low risk and high effectiveness. The significance of this study is limited by small sample size and short follow-up period. Further controlled prospective studies are needed to evaluate the exact effects and long-term outcomes of this treatment method

Other studies have been performed that indicate that surgical treatment may be an effective treatment for patients with occipital neuralgia and cervicogenic headaches; however, these studies had small sample sizes or did not have control groups (Jansen, 2000; Bovim, 1992; Pikus and Phillips, 1996; Kapoor, 2003; Gille, 2004).

Nerve Decompression and Occipital Neurectomy for Headaches

Guyuron et al. (2011) assessed the long-term efficacy of surgical deactivation of migraine headache trigger sites. One hundred twenty-five volunteers were randomly assigned to the treatment (n = 100) or control group (n = 25) after examination by the team neurologist to ensure a diagnosis of migraine headache. Patients were asked to complete the Medical Outcomes Study 36-Item Short Form Health Survey, Migraine-Specific Quality of Life, and Migraine Disability Assessment questionnaires before treatment and at 12- and 60-month postoperative follow-up. The treatment group received botulinum toxin to confirm the trigger sites; controls received saline injections. Treated patients underwent surgical deactivation of trigger site(s). Eighty-nine of 100 patients in the treatment group underwent surgery, and 79 were followed for 5 years. Ten patients underwent deactivation of additional (different) trigger sites during the follow-up period and were not included in the data analysis. The final outcome with or without inclusion of these 10 patients was not statistically different. Sixty-one (88 percent) of 69 patients experienced a positive response to the surgery after 5 years. Twenty (29 percent) reported complete elimination of migraine headache, 41 (59 percent) noticed a significant decrease, and eight (12 percent) experienced no significant change. When compared with the baseline values, all measured variables at 60 months improved significantly. Based on the 5-year follow-up data, the authors concluded that there is strong evidence that surgical manipulation of one or more migraine trigger sites can successfully eliminate or reduce the frequency, duration, and intensity of migraine headache in a lasting manner. This study is of limited significance because no statistical comparisons were made at the 5 year follow-up and patient-reported data may have introduced recall bias in the study.

A randomized trial of patients with medication-refractory, but BT-responsive, migraine headaches compared the removal of the glabellar muscles (n=19), removal of the zygomaticotemporal branch of the trigeminal nerve (n=19), or greater occipital neurectomy (n=11) with sham-control patients (n=26) who underwent only exposure at one of the sites. At 1-year follow-up, complete resolution of headaches was found in 57.1% and significant improvement in 83.7% of patients undergoing actual surgery, and significant improvement was found compared with baseline values in all migraine headache measures. In the sham surgery group, 57.7% of patients reported at least 50% reduction in migraine headache. The difference between experimental and control

groups was statistically significant (Guyuron et al., 2009). These findings require confirmation in a larger study.

Ducic et al. (2013) systematically compared the outcomes of different types of interventional procedures offered for the treatment of headaches and targeted toward peripheral nerves based on available published literature. The objective of this study was to systematically review the literature to compare the published outcomes and effectiveness of peripheral nerve surgery, radiofrequency (RF) therapy, and peripheral nerve stimulators for chronic headaches, migraines, and occipital neuralgia. A total of 26 studies met the inclusion criteria. Of these, 14 articles studied nerve decompression, 9 studied peripheral nerve stimulation, and 3 studied RF intervention. When study populations and results were pooled, a total of 1253 patients had undergone nerve decompression with an 86% success rate. The authors concluded that of the 3 most commonly encountered interventional procedures for chronic headaches, peripheral nerve surgery via decompression of involved peripheral nerves has been the best-studied modality in terms of total number of studies, level of evidence of published studies, and length of follow-up. Reported success rates for nerve decompression or excision tend to be higher than those for peripheral nerve stimulation or for RF, although poor study quantity and quality prohibit an accurate comparative analysis. Although peripheral nerve surgery seems to be the interventional treatment modality that is currently best supported by the literature, better controlled and normalized high-quality studies will help to better define the specific roles for each type of intervention.

Other studies have been performed that indicate that surgery may be an effective treatment for patients with headaches; however, these studies had small sample sizes or no control groups (Williams, 2010; Poggi, 2008; Janis, 2011).

In an effort to draw attention to tests and procedures associated with low-value care in headache medicine, the American Headache Society (AHS) joined the Choosing Wisely initiative of the American Board of Internal Medicine Foundation. One of the recommendations approved by the Choosing Wisely task force of the AHS was do not recommend surgical deactivation of migraine trigger points outside of a clinical trial (Loder et al. 2013).

The American Headache Society has issued a statement about surgical intervention in migraine treatment that indicates that surgery for migraine is a last-resort option and is probably not appropriate for most sufferers. According to the American Headache Society, there are no convincing or definitive data, to date, that show its long-term value. Besides replacing the use of more appropriate treatments, surgical intervention also may produce side effects that are not reversible and carry the risks associated with any surgery (AHS 2012).

Radiofrequency Ablation

In a randomized controlled trial of 30 patients with cervicogenic headache, 15 patients received radiofrequency (RF) treatments, and 15 patients underwent local injections of the greater occipital nerve followed by transcutaneous electrical nerve stimulation when necessary. There were no significant differences between the 2 treatment groups at any time during the study. Eight weeks after the initial treatment, 80% of the patients in the RF-group (Group I) and 66,7% of the patients in the local injection group (Group II) reported a successful treatment in terms of a positive global perceived effect and/or an visual analogue scale (VAS) reduction of at least 50% compared to the initial VAS. Sixteen weeks after the initial treatment, the success rate in Group I was 66,7% compared to 55,3% in Group II. After one year, there was no difference of the success rate in Group I (53,3%) compared to Group II (50%). A relatively high percentage of patients (33,3%) in both groups were not followed anymore because of several reasons. The most important reason was the disappointment in the treatment (Haspeslagh, 2006).

In a randomized, double-blind trial, Lord et al. (1996) compared percutaneous radio-frequency neurotomy in which multiple lesions were made with a control treatment using an identical procedure except that the radio-frequency current was not turned on. The trial included 24

patients who had pain in one or more cervical zygapophyseal joints. The source of the pain had been identified with the use of double-blind, placebo-controlled local anesthesia. Twelve patients received each treatment. The patients were followed by telephone interviews and clinic visits until they reported that their pain had returned to 50 percent of the preoperative level. The median time that elapsed before the pain returned to at least 50 percent of the preoperative level was 263 days in the active-treatment group and 8 days in the control group. At 27 weeks, seven patients in the active-treatment group and one patient in the control group were free of pain. Five patients in the active-treatment group had numbness in the territory of the treated nerves, but none considered it troubling. The authors concluded that in patients with chronic cervical zygapophyseal-joint pain confirmed with double-blind, placebo-controlled local anesthesia, percutaneous radio-frequency neurotomy with multiple lesions of target nerves can provide lasting relief. This study is limited by a small sample size. The authors also stated that radio-frequency neurotomy provided lasting, complete relief, but only in a moderate proportion of patients.

Stovner et al. (2004) conducted a randomized, sham-controlled study of 12 patients with cervicogenic headaches. Six patients underwent radiofrequency neurotomy and six patients received sham treatment. Patients were followed for 2 years. Patients treated with neurotomy were somewhat improved at 3 months, but later follow-up showed no significant differences between the 2 treatment groups.

Ducic et al. (2013) systematically compared the outcomes of different types of interventional procedures offered for the treatment of headaches and targeted toward peripheral nerves based on available published literature. The objective of this study was to systematically review the literature to compare the published outcomes and effectiveness of peripheral nerve surgery, radiofrequency (RF) therapy, and peripheral nerve stimulators for chronic headaches, migraines, and occipital neuralgia. A total of 26 studies met the inclusion criteria. Of these, 14 articles studied nerve decompression, 9 studied peripheral nerve stimulation, and 3 studied RF intervention. When study populations and results were pooled, a total of 1253 patients had undergone nerve decompression with an 86% success rate, 184 patients were treated by nerve stimulation with a 68% success rate, and 131 patients were treated by RF with a 55% success rate. The authors concluded that although peripheral nerve surgery seems to be the interventional treatment modality that is currently best supported by the literature, better controlled and normalized high-quality studies will help to better define the specific roles for each type of intervention.

Vanelderen et al. (2010) reported on the results of a prospective trial with 6 months of follow-up in which pulsed radiofrequency treatment of the greater and/or lesser occipital nerve was used to treat occipital neuralgia in 19 patients. Patients presenting with clinical findings suggestive of occipital neuralgia and a positive test block of the occipital nerves with 2 mL of local anesthetic underwent a pulsed radiofrequency procedure of the culprit nerves. Approximately 52.6% of patients reported a score of 6 (pain improved substantially) or higher on the Likert scale after 6 months. No complications were reported. The investigators concluded that pulsed radiofrequency treatment of the greater and/or lesser occipital nerve is a promising treatment of occipital neuralgia. This study warrants further placebo-controlled trials.

Huang et al. (2012) conducted a retrospective data analysis to evaluate the use of pulsed radiofrequency (PRF) for occipital neuralgia (ON) in 102 patients. Fifty-two (51%) patients experienced $\geq 50\%$ pain relief and satisfaction with treatment lasting at least 3 months. Variables associated with a positive outcome included a traumatic inciting event, lower diagnostic block volumes, and employment of multiple rounds of PRF. Factors correlating with treatment failure included extension of pain anterior to the scalp apex and ongoing secondary gain issues. The authors concluded that PRF may provide intermediate-term benefit for ON in a significant proportion of refractory cases. The authors stated that careful attention to selection criteria and treatment parameters may further improve treatment outcomes. The significance of these findings is limited due to the retrospective design of the study and short follow-up time.

Halim et al. (2010) conducted a retrospective study that included 86 patients who had undergone lateral C1-2 joint pulsed radiofrequency application, for cervicogenic headache in a single pain center from March 2007 to December 2008. The percentage of patients who had $\geq 50\%$ pain relief at 2 months, 6 months, and 1 year were 50% (43/86), 50% (43/86), and 44.2% (38/86), respectively. Long-term pain relief at 6 months and 1 year were predicted reliably by $\geq 50\%$ pain relief at 2 months. Apart from 1 patient that complained of increased severity of occipital headache lasting several hours, there were no other reported complications. The lack of a control group limits the validity of the results of this study.

Other studies have been performed that indicate that radiofrequency ablation may be an effective treatment for patients with headaches; however, these studies had small sample sizes or no control groups (Narouze, 2009; Govin, 2003; Lee, 2007). No clinical trials were identified that evaluated radiofrequency ablation for the treatment of migraine headaches.

Neurostimulation or Electrical Stimulation for Headaches

Silberstein et al. (2012) conducted a randomized, controlled multicenter study that included 157 patients diagnosed with chronic migraine (CM) who were implanted with a peripheral nerve stimulation device near the occipital nerves and randomized 2:1 to active ($n = 105$) or sham ($n = 52$) stimulation. The primary endpoint was a difference in the percentage of responders (defined as patients that achieved a $\geq 50\%$ reduction in mean daily visual analog scale scores) in each group at 12 weeks. There was not a significant difference in the percentage of responders in the active compared with the control group. However, there was a significant difference in the percentage of patients that achieved a 30% reduction. Compared with sham-treated patients, there were also significant differences in reduction of number of headache days (Active Group = 6.1; Control Group = 3.0), migraine-related disability, and direct reports of pain relief. The most common adverse event was persistent implant site pain. The authors concluded that although this study failed to meet its primary endpoint, this is the first large-scale study of PNS of the occipital nerves in CM patients that showed significant reductions in pain, headache days, and migraine-related disability. The authors stated that additional controlled studies using endpoints that have recently been identified and accepted as clinically meaningful are warranted in this highly disabled patient population.

Schoenen et al. (2013a) conducted a randomized, sham-controlled multicenter study of an implantable on-demand sphenopalatine ganglion (SPG) neurostimulator in patients suffering from refractory chronic cluster headache (CCH). Each CH attack was randomly treated with full, sub-perception, or sham stimulation. Pain relief at 15 minutes following SPG stimulation and device- or procedure-related serious adverse events (SAEs) were evaluated. Thirty-two patients were enrolled and 28 completed the randomized experimental period. Pain relief was achieved in 67.1% of full stimulation-treated attacks compared to 7.4% of sham-treated and 7.3% of sub-perception-treated attacks. Nineteen of 28 (68%) patients experienced a clinically significant improvement: seven (25%) achieved pain relief in $\geq 50\%$ of treated attacks, 10 (36%), a $\geq 50\%$ reduction in attack frequency, and two (7%), both. Five SAEs occurred and most patients (81%) experienced transient, mild/moderate loss of sensation within distinct maxillary nerve regions; 65% of events resolved within three months. The serious adverse events involved neurostimulator lead misplacement in three patients and neurostimulator lead migration in two. The authors concluded that on-demand SPG stimulation using the ATI Neurostimulation System is an effective novel therapy for CCH sufferers, with dual beneficial effects, acute pain relief and observed attack prevention, and has an acceptable safety profile compared to similar surgical procedures. The significance of this study is limited by its small sample size.

Schoenen et al. (2013b) assessed efficacy and safety of trigeminal neurostimulation with a supraorbital transcutaneous stimulator (Cefaly, STX-Med., Herstal, Belgium) in migraine prevention in a double-blinded, randomized, sham-controlled trial conducted at 5 Belgian tertiary headache clinics. After a 1-month run-in, patients with at least 2 migraine attacks/month were randomized 1:1 to verum or sham stimulation, and applied the stimulator daily for 20 minutes

during 3 months. Primary outcome measures were change in monthly migraine days and 50% responder rate. Sixty-seven patients were randomized and included in the intention-to-treat analysis. Between run-in and third month of treatment, the mean number of migraine days decreased significantly in the verum (6.94 vs 4.88), but not in the sham group (6.54 vs 6.22). The 50% responder rate was significantly greater in the verum (38.1%) than in the sham group (12.1%). Monthly migraine attacks, monthly headache days, and monthly acute antimigraine drug intake were also significantly reduced in the verum but not in the sham group. There were no adverse events in either group. The authors concluded that supraorbital transcutaneous stimulation with the device used in this trial is effective and safe as a preventive therapy for migraine. The therapeutic gain (26%) is within the range of those reported for other preventive drug and nondrug antimigraine treatments. Further research is needed to determine the clinical relevance of these findings and to evaluate if treatment-resistant chronic migraine patients would benefit from supraorbital transcutaneous stimulation.

Saper et al. (2011) conducted a multicenter, randomized, blinded, controlled feasibility study to obtain preliminary safety and efficacy data on occipital nerve stimulation (ONS) in chronic migraine (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 three-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%) patients. According to the authors, the results of this feasibility study offer promise and should prompt further controlled studies of ONS in CM. The authors stated that this study was not prospectively powered for efficacy evaluation.

Serra et al. (2012) conducted a prospective, randomized cross-over study to investigate the safety and efficacy of occipital nerve stimulation (ONS) for chronic migraine (CM) and medication overuse headache (MOH). Patients who responded to a stimulation trial underwent device implantation and were randomized to "Stimulation On" and "Stimulation Off" arms. Patients crossed over after one 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 one-year follow-up. Twenty-nine patients completed the study. Headache intensity and frequency were significantly lower in the On arm than in the Off arm and decreased from the baseline to each follow-up visit in all patients with Stimulation On. Quality of life significantly improved during the study. Triptans and nonsteroidal 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 one year). Five adverse events occurred and included 2 infections and 3 lead migrations. The authors concluded that ONS appears to be a safe and effective treatment for carefully selected CM and MOH patients. Author-noted limitations included single-center study, relatively small number of patients, and absence of a control group.

Ducic et al. (2013) systematically compared the outcomes of different types of interventional procedures offered for the treatment of headaches and targeted toward peripheral nerves based on available published literature. The objective of this study was to systematically review the literature to compare the published outcomes and effectiveness of peripheral nerve surgery, radiofrequency (RF) therapy, and peripheral nerve stimulators for chronic headaches, migraines, and occipital neuralgia. A total of 26 studies met the inclusion criteria. Of these, 14 articles studied nerve decompression, 9 studied peripheral nerve stimulation, and 3 studied RF intervention. When study populations and results were pooled, a total of 1253 patients had undergone nerve decompression with an 86% success rate, 184 patients were treated by nerve stimulation with a 68% success rate, and 131 patients were treated by RF with a 55% success rate. Neither nerve decompression nor RF reported complications requiring a return to the operating room, whereas implantable nerve stimulators had a 31.5% rate of such complications.

The authors concluded that although peripheral nerve surgery seems to be the interventional treatment modality that is currently best supported by the literature, better controlled and normalized high-quality studies will help to better define the specific roles for each type of intervention.

In a systematic review, Jasper and Hayek (2008) evaluated the strength of evidence that occipital nerve stimulation (ONS) is an effective treatment of chronic headache. Ten observational studies, of which 4 were prospective, and a number of case series, case reports, and reviews were identified. No randomized controlled trials (RCT) were identified. All of the studies reported positive outcomes including improved pain relief, reduced frequency, intensity, and duration of headaches with reduced medication consumption. ONS was reportedly successful for 70 to 100% of patients. Reduction of pain in patients with occipital headaches and transformed migraine is significant and rapid; for cluster patients the improvement may be less dramatic and it may take several months of occipital stimulation to achieve relief. No long-term adverse events occurred. Several short-term adverse events occurred including infection, lead displacement, and battery depletion. The body of evidence as a whole is a level of strength of IV (limited).

Vadivelu et al. (2011) evaluated 18 patients with Chiari I malformation (CMI) and persistent occipital headaches who underwent occipital neurostimulator trials and, following successful trials, permanent stimulator placement. Seventy-two percent (13/18) of patients had a successful stimulator trial and proceeded to permanent implant. Of those implanted, 11/13 (85%) reported continued pain relief at a mean follow-up of 23 months. Device-related complications requiring additional surgeries occurred in 31% of patients. According to the authors, occipital neuromodulation may provide significant long-term pain relief in selected CMI patients with persistent occipital pain. The authors state that larger and longer-term studies are needed to further define appropriate patient selection criteria as well as to refine the surgical technique to minimize device-related complications.

Popeney et al. (2003) evaluated the responses to C1 through C3 peripheral nerve stimulation in an uncontrolled consecutive case series of 25 patients with transformed migraine. Prior to stimulation, all patients experienced severe disability with 75.56 headache days over a 3-month period. Following stimulation, 15 patients reported little or no disability, 1 reported mild disability, 4 reported moderate disabilities, and 5 continued with severe disability, with 37.45 headache days. The average improvement in the MIDAS score was 88.7%, with all patients reporting their headaches well controlled after stimulation. The authors concluded that these results raise the possibility that C1 through C3 peripheral nerve stimulation can help improve transformed migraine symptoms and disability. The authors stated that a controlled study is required to confirm these results.

Magis et al. (2011) evaluated 15 patients with drug-resistant chronic cluster headache (drCCH) who were implanted with suboccipital stimulators on the side of their headache. Long-term follow-up was achieved by questionnaires or by phone interviews. Mean follow-up time post-surgery was 36.82 months (range 11 - 64 months). One patient had an immediate post-operative infection of the material. Among the 14 remaining patients, 11 (i.e., 80%) had at least a 90% improvement with 60% becoming pain-free for prolonged periods. Two patients did not respond or described mild improvement. According to the authors, long-term follow-up confirms the efficacy of ONS in drCCH, which remains a safe and well-tolerated technique. These findings require confirmation in a larger study.

Other studies have been performed that indicate that neurostimulation or electrical stimulation may be an effective treatment for patients with cluster headaches or other headaches; however, these studies had small sample sizes with no control groups (Brewer et al., 2012; Schwedt et al., 2007; Reed et al., 2010; Fontaine et al., 2011; Mueller et al., 2011; Ansarinia et al., 2010; Melvin et al., 2007; Magis et al., 2007; Ahmed et al., 2000; Kapural et al. 2005).

In a National Institute for Health and Care Excellence (NICE) Guidance for occipital nerve stimulation for intractable chronic migraine, NICE stated that the evidence on occipital nerve stimulation (ONS) for intractable chronic migraine shows some efficacy in the short term but there is very little evidence about long-term outcomes. With regard to safety, there is a risk of complications, needing further surgery. Therefore NICE recommends that this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. NICE encourages publication of further information from comparative studies and from collaborative data collection to guide future use of this procedure and to provide patients with the best possible advice (NICE 2013).

Neurostimulation or Electrical Stimulation for Occipital Neuralgia

Slavin et al. (2006) analyzed the records of 14 consecutive patients with intractable occipital neuralgia treated with peripheral neurostimulation. Ten patients proceeded with system internalization after a 50% pain reduction during the trial period. Two patients had their systems explanted because of loss of stimulation effect or significant improvement of pain, and one patient had part of his hardware removed because of infection. The authors concluded that overall, the beneficial effect from chronic stimulation persisted in more than half of the patients for whom the procedure was considered and in 80% of those who significantly improved during the trial and proceeded with internalization. These findings require confirmation in a larger study.

Amin et al. (2008) evaluated the efficacy of supraorbital nerve stimulation for treatment of intractable supraorbital neuralgia in a case series of 16 patients. The patients underwent a trial of supraorbital nerve stimulation, and efficacy was assessed after 5-7 days. Ten patients consented to undergo permanent implantation of the stimulator. Opioid consumption and headache scores were monitored preoperatively and at timed intervals for 30 weeks. Headache scores decreased, and opioid consumption was reduced in half, and these beneficial accomplishments were maintained up to 30 weeks after implantation. This study is limited by a short follow-up.

Other studies have been performed that indicate that neurostimulation or electrical stimulation may be an effective treatment for patients with occipital neuralgia; however, these studies had small sample sizes with no control groups (Weiner and Reed 1999; Johnstone and Sundaraj, 2006).

The 2011 Hayes Technology Brief on electrical stimulation of the occipital nerve for the treatment of occipital neuralgia summarized the available evidence stating that the results of the available studies provide preliminary evidence that subcutaneous electrical stimulation of the greater and lesser occipital nerves offers long-term relief in some patients who have intractable occipital neuralgia. Although the available studies of this technique are small and uncontrolled, most of the patients had experienced symptoms of occipital neuralgia for more than 2 years and had failed to respond adequately to optimal conservative treatments. The overall quality of the evidence is low since the studies are all small in size and none of them compared the outcomes of patients treated with occipital nerve stimulation (ONS) with patients in a control group. Since occipital neuralgia is a rare disorder, it does not seem feasible to conduct large-scale, randomized controlled trials to evaluate the efficacy of electrical stimulation therapy versus other standard therapies. Furthermore, while a study that included randomizing patients to optimal medical therapy versus ONS would be ideal, the patients who are good candidates for ONS are usually referred because they have failed optimal medical therapy. Larger studies with longer periods of follow-up are needed to confirm the benefits reported in the available studies. (Hayes, 2011).

Professional Societies

American Society of Anesthesiologists (ASA)/American Society of Regional Anesthesia and Pain Medicine (ASRA): In practice guidelines created jointly in 2010, the American Society of Anesthesiologists (ASA) and American Society of Regional Anesthesia and Pain Medicine (ASRA) state the following (ASA/ASRA, 2010): Subcutaneous peripheral nerve stimulation may

be used in the multimodal treatment of patients with painful peripheral nerve injuries who have not responded to other therapies.”

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Local Injection Therapy: Various local anesthetics are approved by the FDA for use in diagnostic and therapeutic nerve blockade. Botulinum toxin-A (BTX-A or BOTOX) is a neurolytic agent that has also been approved by the FDA for treatment of some conditions. However, BTX-A is not specifically approved for treatment of cervicogenic headache or occipital neuralgia; the use of BTX-A for these diagnoses is off-label use. Additional information is available at: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm070366.htm>. Accessed January 2014.

Radiofrequency Ablation (RFA): RFA is a procedure and, therefore, is not subject to regulation by the FDA. However, the devices used to perform RFA are regulated by the FDA premarket approval process. There are numerous devices listed in the FDA 510(k) database approved for use in performing RFA. Two product codes are dedicated to these devices, one for radiofrequency lesion generators (GXD) and one for radiofrequency lesion probes (GXI). Additional information is available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>. Accessed January 2014.

Electrical Stimulation: Electrical stimulation of the occipital nerve for the treatment of occipital neuralgia and cervicogenic headache is a procedure and, therefore, not subject to regulation by the FDA; however, the devices used to perform electrical stimulation are regulated via the FDA 510(k) premarket approval process. The Renew™ Quattro® device received 510(k) approval (K000852) on January 19, 2001, and the Pisces Quad® device was approved (K040568) on March 25, 2004. Additional information is available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>. Accessed January 2014.

Currently no implantable pulse generator, radiofrequency device, or leads are approved by the FDA for peripheral occipital nerve stimulation to treat occipital neuralgia or headaches.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) that specifically addresses injections of local anesthetics and/or steroids used as occipital nerve blocks for the treatment of pain due to malignancy involving the head and neck. Local Coverage Determinations (LCDs) do exist. Refer to the following LCDs:

- [Nerve Blockade: Somatic Selective Nerve Root and Epidural](#)
- [Noncovered Services](#)
- [Non-Covered Services](#)
- [Pain Management](#)
- [Peripheral Nerve and Peripheral Nerve Field Stimulation](#)
- [Peripheral Nerve Blocks](#)
- [Services That Are Not Reasonable and Necessary](#)
- [Spinal Cord Stimulation \(Dorsal Column Stimulation\)](#)
- [Surgical Decompression for Peripheral Polyneuropathy](#)

(Accessed February 21, 2014)

Medicare does not have a National Coverage Determination (NCD) that specifically addresses injections of local anesthetics and/or steroids used as occipital nerve blocks for the diagnosis and treatment of occipital neuralgia or headaches. Local Coverage Determinations (LCDs) do exist. Refer to the following LCDs:

- [Nerve Blockade: Somatic Selective Nerve Root and Epidural](#)
- [Noncovered Services](#)

- [Non-Covered Services](#)
- [Pain Management](#)
- [Peripheral Nerve and Peripheral Nerve Field Stimulation](#)
- [Peripheral Nerve Blocks](#)
- [Services That Are Not Reasonable and Necessary](#)
- [Spinal Cord Stimulation \(Dorsal Column Stimulation\)](#)
- [Surgical Decompression for Peripheral Polyneuropathy](#)

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POLICY HISTORY/REVISION INFORMATION

| Date | Action/Description |
|------------|--|
| 09/01/2014 | <ul style="list-style-type: none"> • Changed policy title; previously titled <i>Occipital Neuralgia and Cervicogenic, Cluster and Migraine Headaches</i> • Reorganized policy content • Added reference link to policies titled <i>Ablative Treatment for Spinal Pain and Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements</i> • Revised coverage rationale: <ul style="list-style-type: none"> ○ Added language to indicate injection of local anesthetics and/or steroids, used as occipital nerve blocks, is proven and medically necessary for the treatment of pain due to malignancy involving the head and neck ○ Added language to indicate the unproven services are “not medically necessary” |

| Date | Action/Description |
|------|---|
| | <ul style="list-style-type: none"> • Updated list of applicable CPT codes; removed 64569, 64802 and 64804 • Added list of applicable ICD-9 diagnosis codes: 338.3 • Added list of applicable ICD-10 diagnosis codes (preview draft effective 10/01/15): G89.3 • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references • Archived previous policy version 2014T0080M |