INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

CONDITIONS OF COVERAGE

<table>
<thead>
<tr>
<th>Applicable Lines of Business/Products</th>
<th>This policy applies to Oxford Commercial plan membership.</th>
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<tbody>
<tr>
<td>Benefit Type</td>
<td>General benefits package</td>
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<tr>
<td>Referral Required</td>
<td>No</td>
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<tr>
<td>(Does not apply to non-gatekeeper products)</td>
<td>Yes¹</td>
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<tr>
<td>Authorization Required</td>
<td>No</td>
</tr>
<tr>
<td>(Precertification always required for inpatient admission)</td>
<td></td>
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<tr>
<td>Precertification with Medical Director Review Required</td>
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</tr>
<tr>
<td>Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)</td>
<td>¹Precertification is required for services covered under the Member's General Benefits package when performed in the office of a participating provider. For Commercial plans, precertification is not required, but is encouraged for out-of-network services performed in the office that are covered under the Member's General Benefits package. If precertification is not obtained, Oxford may review for medical necessity after the service is rendered.</td>
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 BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

**Essential Health Benefits for Individual and Small Group**

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

**COVERAGE RATIONALE**

**Injection of local anesthetics and/or steroids, used as occipital nerve blocks, is proven and medically necessary for treating 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 diagnosing and treating 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.

Refer to 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 treating 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 headache. The long-term efficacy of surgical procedures for occipital neuralgia or cervicogenic headache has not been established in well-designed clinical trials.

**Occipital neurectomy or surgical nerve decompression is unproven and not medically necessary treating 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 treating occipital neuralgia or headaches including migraine, cluster and cervicogenic headaches.**

The available evidence from published studies is not sufficient to conclude that radiofrequency ablation or denervation is an effective treatment for occipital neuralgia or cervicogenic headache. 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 treating occipital neuralgia or headaches including migraine, cluster and cervicogenic headaches.**

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 cervicogenic 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 following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan 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 claim payment. Other Policies may apply.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0282T</td>
<td>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</td>
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<td>0283T</td>
<td>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</td>
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<tr>
<td>0284T</td>
<td>Revision or removal of pulse generator or electrodes, including imaging guidance, when performed, including addition of new electrodes, when performed</td>
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<td>0285T</td>
<td>Electronic analysis of implanted peripheral subcutaneous field stimulation pulse generator, with reprogramming when performed</td>
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<td>63185</td>
<td>Laminectomy with rhizotomy; 1 or 2 segments</td>
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<tr>
<td>63190</td>
<td>Laminectomy with rhizotomy; more than 2 segments</td>
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<tr>
<td>64405</td>
<td>Injection, anesthetic agent; greater occipital nerve</td>
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<tr>
<td>64553</td>
<td>Percutaneous implantation of neurostimulator electrode array; cranial nerve</td>
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<tr>
<td>64555</td>
<td>Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)</td>
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<td>64568</td>
<td>Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator</td>
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<tr>
<td>64570</td>
<td>Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator</td>
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<tr>
<td>64575</td>
<td>Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)</td>
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<td>64590</td>
<td>Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling</td>
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<td>64633</td>
<td>Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint</td>
</tr>
<tr>
<td>64634</td>
<td>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)</td>
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<td>Decompression; unspecified nerve(s) (specify)</td>
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<td>64744</td>
<td>Transection or avulsion of; greater occipital nerve</td>
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<tr>
<td>64771</td>
<td>Transection or avulsion of other cranial nerve, extradural</td>
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<tr>
<td>64999</td>
<td>Unlisted procedure, nervous system</td>
</tr>
<tr>
<td>95972</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode select ability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming</td>
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</tbody>
</table>

*CPT® is a registered trademark of the American Medical Association*
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, 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 cervicogenic 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.


**Therapeutic Occipital Nerve Blocks**
Palamar et al. (2015) performed a prospective, randomized, placebo-controlled, double-blind pilot trial to compare the effectiveness of ultrasound-guided greater occipital nerve block (GONB) using bupivacaine 0.5% and placebo on clinical improvement in patients with refractory migraine without aura (MWOA). Thirty-two patients with a diagnosis of MWOA were randomly assigned to receive either GONB with local anesthetic (bupivacaine 0.5% 1.5 mL) or greater occipital nerve (GON) injection with normal saline (0.9% 1.5 mL). The treatment group consisted of 11 patients and the placebo group was comprised of 12 patients. The ultrasound-guided GONB was performed to accurately locate the nerve. Headache severity was assessed with the visual analogue scale (VAS) from 0 (no pain) to 10 (intense pain). In
both groups, a decrease in headache intensity on the injection side was observed during the first post-injection week and continued until the second week. After the second week in the treatment group, the improvement continued and the VAS score was increased at the end of the fourth week. In the placebo group the VAS score increased and nearly reached the pre-injection levels after the second week. The decrease in the monthly average pain intensity score on the injected side was statistically significant in the treatment group, but not in the placebo group. The authors noted that ultrasound guided GONB with bupivacaine for the treatment of migraine patients is a safe, simple, and effective technique without severe adverse effects. This trial included a small sample with a short follow-up duration. Patients were followed for one month after the injection, so long-term effects of the injection have not been observed.

In a multicenter, double-blind, randomized placebo-controlled crossover trial, Inan et al. (2015) evaluated the safety and efficacy of unilateral GONB (greater occipital nerve block) in 84 patients with chronic migraine at 1, 2, and 3 month follow-up. Patients were randomly assigned to either an intervention group (A) and received GONB with injections of 0.5% bupivacaine (n=42) or a placebo group (B) receiving 2.5 mL saline (n=42) once a week for 4 weeks. After 4 weeks, the study was unblinded and patients in the placebo group were crossed over to GONB with bupivacaine once per week for 8 weeks. Patients in the intervention group were followed for 4 weeks, and GONB was repeated with bupivacaine. After 1 month of treatment, the number of headache days had decreased from 16.9 ± 5.7 to 13.2 ± 6.7 in group A and from 18.1 ± 5.3 to 8.8 ± 4.8 in group B. The mean duration of headache (hours) had decreased from 25.9 ± 16.3 to 19.3 ± 11.5 in group A and from 24.2 ± 13.7 to 21.2 ± 13.4 in group B. The VAS score was significantly lower in the intervention group. After 2 months of treatment, when the placebo group received active treatment, the mean number of headache days decreased to 6.6 ± 4.7 in group A and to 8.4 ± 5.0 in group B. After 3 months, headache frequency had decreased significantly in group A (5.5 ± 4.0), and in group B (6.7 ± 5.2) but the difference between the groups was not significant. The mean duration of headache (hours) had decreased to 14.0 ± 10.4 in the group A, and to 15.1 ± 8.9 in group B. The difference was not significant between the groups. After 3 months of treatment, the hours had declined further to a mean of 10.0 ± 6.2 in group A, and 10.8 ± 5.9 in group B but again, the difference was not significant between the two groups. The mean VAS score improved in both the intervention and placebo groups with similar improvements in the two groups. The authors stated the evidence suggests that GONB with bupivacaine relieves migraine headache symptoms and reduces the frequency of the attacks compared with a placebo. This was confirmed when the placebo patients crossed over to active treatment and experienced significant symptom relief. The study is limited by its small sample size, short follow-up time, and short duration of the double-blind phase.

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 anesthetic 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.

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 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; Updated 2015).

Voigt and Murphy (2015) conducted a systematic literature review of the available evidence regarding the use of occipital nerve blocks (ONBs) for the management of acute headaches, and then determined its potential for use in the emergency care setting. Techniques, medication selection, adverse reactions, frequency of use, candidates, and measures that can help improve safety were reviewed in order to better evaluate the usefulness of this tool in emergency care. The authors utilized the U.S. Preventive Services Task Force grading of evidence definitions and created the following grades based on available research for the use of ONBs in the treatment of various types of headaches: Cluster headache B (Moderate), Cervicogenic headache B (Moderate), Migraine headache C (Low), Tension-type headache I (Insufficient evidence), Hemicrania continua I (Insufficient evidence), and Chronic daily headache C (Low). The authors concluded that current evidence supports that ONBs can be delivered safely in an outpatient setting by providers who have been trained in and have practiced this procedure. According to the authors, current evidence supports that ONBs can be useful in treating acute headaches in an emergency care setting although additional research is needed.

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.

Lambru et al. (2014) 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.

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 anesthetic 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 anesthetic 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.

Naja et al. (2009) also 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 symptomatic medication overuse (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.

Dilli et al. (2014) evaluated the efficacy of ONB with local anesthetic and corticosteroid for the preventive treatment of migraine. Patients between 18 and 75 years old with International Classification of Headache Disorders (ICHD)-defined episodic (> 1 attack per week) or chronic migraine were randomized to receive either 2.5 ml 0.5% bupivacaine plus 0.5 ml (20 mg) methylprednisolone over the ipsilateral (unilateral headache) or bilateral (bilateral headache) occipital nerve (ON) or 2.75 ml normal saline plus 0.25 ml 1% lidocaine without epinephrine (placebo). Patients completed a one-month headache diary prior to and after the double-blind injection. The primary outcome measure was defined as a 50% or greater reduction in the frequency of days with moderate or severe migraine headache in the four-week post-injection compared to the four-week pre-injection baseline period. Thirty-four patients received active and 35 patients received placebo treatment. Because of missing data, the full analysis of 33 patients in the active and 30 patients in the placebo group was analyzed for efficacy. In the active and placebo groups respectively, the mean frequency of at least moderate (mean 9.8 versus 9.5) and severe (3.6 versus 4.3) migraine days and acute medication days (7.9 versus 10.0) were not substantially different at baseline. The percentage of patients with at least a 50% reduction in the frequency of moderate or severe headache days was 30% for both groups. The authors concluded that greater ONB does not reduce the frequency of moderate to severe migraine days in patients with episodic or chronic migraine compared to placebo.

Kashipazha et al. (2014) conducted a randomized double-blinded controlled trial to evaluate the therapeutic efficacy of greater occipital nerve block (GONB) on 48 patients suffering from migraine headaches. A syringe containing 1.0 mL of lidocaine 2%, 0.5 mL of either saline (control group, N = 24) or triamcinolone 0.5 mL (intervention group, N = 24) was prepared for each patient. Patients were assessed prior to the injection, and also 2 weeks, 1 month, and 2 months thereafter for severity and frequency of pain, times to use analgesics and any appeared side effects. No significant differences were revealed in pain severity, pain frequency, and analgesics use between the two groups at the four study time points including at baseline, and 2, 4, and 8 weeks after the intervention. However, in both groups, the indices of pain severity, pain frequency, and analgesics use were significantly reduced at the three time points after the intervention compared with before the intervention. The authors concluded that GONB with triamcinolone in combination with lidocaine or normal saline with lidocaine results in reducing pain severity and frequency as well as use of analgesics up to two months after the intervention; however, any difference attributed to the drug regimen by assessing of the trend of pain characteristics changes. These findings require confirmation in a larger study.

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 (Lauretti, 2014; Niraj, 2014; Govindappagari, 2014; Seeger, 2014; Guerrero, 2012; Young, 2008; Akin, 2008.

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 for Adult Cancer Pain indicate that interventional therapies that can be useful in the relief of cancer pain include nerve blocks (2014, Updated 2016).

**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
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.

Choi et al. (2015) performed a retrospective analysis in 68 patients with medically refractory occipital neuralgia who underwent C2 ganglion decompression for intractable occipital neuralgia. All patients had failed to respond to conservative management, including combination pharmacotherapy, steroids or a Botox injection, acupuncture, and physical therapy. The average duration of symptoms prior to surgery was 13.7 years. Pain was assessed before C2 anesthetic blockade and after 1 year and 5 years following surgery, and therapeutic success was defined as pain relief by at least 50% without ongoing medication. All the patients experienced temporary pain relief after surgical decompression; however, two patients experienced recurrence within a week after the operation. At the 1-year follow-up, 57 patients (83.8%) had more than 50% pain relief. Of 57 patients, 12 experienced an excellent result (no headache) and 45 had a good result (headache relief more than 50%). The remaining 11 patients experienced recurrence of symptoms as a poor result (headache relief less than 50%), even if they experienced adequate pain relief after the operation. At the 5-year follow-up, 55 patients had excellent or good results and 13 patients with poor results were identified. The long-term outcome after 5 years was only slightly less than the 1-year outcome; 47 of the 68 patients (69.1%) obtained therapeutic success. Longer duration of headache and presence of retro-orbital/frontal radiation were significantly associated with poor prognosis. The authors stated that this current study demonstrated that C2 ganglion decompression provided durable, adequate pain relief with minimal complications in patients suffering from intractable occipital neuralgia. Further study is required to manage the pain recurrence associated with longstanding nerve injury. The study is limited by its retrospective observations.

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 (Ducic, 2014; 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. (2014) 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).

The clinical evidence was reviewed on March 23, 2016 with no additional information identified that would change the unproven conclusion for nerve decompression.

**Radiofrequency Ablation**

Nagar et al. (2015) conducted a systematic review to investigate the clinical utility of radiofrequency (RF) neurotomy, and pulsed RF (PRF) ablation for the management of cervicogenic headache (CHA). The review included relevant literature identified through searches of PubMed, Cochrane, Clinical trials, U.S. National Guideline Clearinghouse and EMBASE from 1960 to January 2014. The focus was on randomized trials and case-control, prospective, cohort, and cross-sectional studies with participants suffering from CHA who had failed conservative management. A study was judged to be positive if the interventions provided headache relief and improved quality of life. There were 5 non-randomized trials among them 4/5 were of moderate quality, 3/5 showed RF ablation and 1/5 showed PRF as an effective intervention for cervicogenic headache. There were 4 randomized trials among them 2/4 were of high quality, 3/4 investigated RF ablation as an intervention for CHA, and 1/4 investigated PRF ablation as an intervention for CHA. None of the randomized studies showed strong evidence for RF and PRF ablation as an effective intervention for CHA. There were 2 RCTs which did not show significant benefits with RFA. There is limited evidence for RF and pulsed RFA therapies for management of CHA. Evidence is insufficient to assess the effects on the health outcomes because of the limited number of studies or the low power of the studies, unexplained inconsistency between RCTs, flaws in trial design, gaps in the chain of evidence, and lack of detailed information on desired health outcomes.

Manolitsis and Elahi (2014) conducted an evidence-based review of the current literature concerning the use of pulsed radiofrequency (PRF) for occipital neuralgia. The authors found that a total of 3 clinical studies and one case report investigating the use of PRF for occipital neuralgia have been published worldwide. Statistically significant improvements in pain, quality of life, and adjuvant pain medication usage have been demonstrated. According to the authors the evidence limitations include lack of randomized control trials, small study sample sizes, an absence of diagnostic block imaging guidance, and the use of outcome measures that are inherently subjective, limiting objectivity and introducing an unquantifiable degree of bias. The authors concluded that clinical studies to date examining the efficacy of PRF as a treatment for occipital neuralgia have yielded promising results, demonstrating sustained improvement in pain, quality of life, and adjuvant pain medication usage. The authors stated that despite these encouraging clinical studies, conclusive evidence in support of PRF as an interventional treatment option for occipital neuralgia awaits to be seen.

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.

Vanelderden 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 ≥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.

Neurostimulation or Electrical Stimulation for Headaches

Dodick et al. (2014) presented 52-week safety and efficacy results of peripheral nerve stimulation (PNS) of the occipital nerves for managing chronic migraine from an open-label extension of a randomized, sham-controlled trial. In this institutional review board-approved, randomized, multicenter, double-blinded study, patients were implanted with a neurostimulation system, randomized to an active or control group for 12 weeks, and received open-label treatment for an additional 40 weeks. Statistical tests assessed change from baseline to 52 weeks using paired t-tests. Intent-to-treat (ITT) analyses of all patients (N = 157) and analyses of only patients who met criteria for intractable chronic migraine (ICM; N = 125) were performed. Headache days were significantly reduced by 6.7 (±8.4) days in the IIT population and by 7.7 (±8.7) days in the ICM population. The percentages of patients who achieved a 30% and 50% reduction in headache days and/or pain intensity were 59.5% and 47.8%, respectively. Migraine disability assessment (MIDAS) and Zung Pain and Distress (PAD) scores were significantly reduced for both populations. Excellent or good headache relief was reported by 65.4% of the ITT population and 67.9% of the ICM population. More than half the patients in both cohorts were satisfied with the headache relief provided by the device. A total of 183 device/procedure-related adverse events occurred during the study, of which 18 (8.6%) required hospitalization and 85 (40.7%) required surgical intervention; 70% of patients experienced an adverse event. The authors concluded that the results of the study supported the 12-month efficacy of PNS of the occipital nerves for headache pain and disability associated with chronic migraine. Because of the significant complication rate, more emphasis on adverse event mitigation is needed in future research.

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 ≥50% of treated attacks, 10 (36%), a ≥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.

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 (Verrills et al., 2014; 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).

In a set of recommendations regarding neuromodulation for the treatment of chronic headaches, the European Headache Federation states that in spite of a growing field of stimulation devices in headaches treatment, further controlled studies to validate, strengthen and disseminate the use of neurostimulation are clearly warranted. The European Headache Federation states that until these data are available any neurostimulation device should only be used in patients with medically intractable syndromes from tertiary headache centers either as part of a valid study or have shown to be effective in such controlled studies with an acceptable side effect profile (Martelletti et al. 2013).

The clinical evidence was reviewed on March 21, 2016 with no additional information identified that would change the unproven conclusion for neurostimulation or electrical stimulation for headaches.

**Neurostimulation or Electrical Stimulation for Occipital Neuralgia**

Chen et al. (2015) conducted a systematic review to examine the effectiveness and adverse effects of occipital nerve stimulation (ONS) for chronic migraine. Five randomized controlled trials (RCTs) (total n=402) and seven case series (total n=115) met the inclusion criteria. All three multicenter RCTs included an initial blinded phase of 12 weeks, during which patients received either active or sham stimulation. Occipital nerve blocks and intraoperative testing were performed in the fourth center. The blinded phase was followed by an open label phase of 1–3 years during which all participants received active stimulation (results not yet published). Baseline migraine days per month were similar across the studies (20 to 23). Patients in the trials had between 19–22 days with prolonged, moderate or severe headache per month at baseline. Those patients receiving sham stimulation had a reduction of 2–4 days per month at three months. Meta-analysis shows that ONS was associated with an additional mean reduction of 2.59 days per month compared with sham control. Serious adverse events occurred in between 1% to 6% of patients in multicenter RCTs at 3 months and lead dislodgement and infections were common and often require revision surgery. Reported infection rates range from 4% to 30% with varied length of follow-up. The authors concluded that current evidence on the effectiveness and safety of ONS is still limited in quantity and remains inconclusive. Further measures to reduce the risk of adverse events and revision surgery are needed. The quantitative analysis was hampered by incomplete publication and reporting of trial data.

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.

Other studies have been performed to 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 (Reed 1999; Johnstone and Sundararaj, 2006).

**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.”

**The Congress of Neurological Surgeons**
The Congress of Neurological Surgeons published an evidence-based guideline in 2015 supporting the use of occipital nerve stimulation as a treatment option for patients with medical refractory occipital neuralgia. The patient population in the nine studies reviewed was small and there was a short duration of follow-up (Sweet, 2015). Class III evidence: Level III recommendation (Evidence from case series, comparative studies with historical controls, case reports, and expert opinion, as well as significantly flawed randomized, controlled trials).

**International Neuromodulation Society (INS)**
The INS board of directors chose an expert panel, the Neuromodulation Appropriateness Consensus Committee (NACC), to evaluate the peer-reviewed literature, current research, and clinical experience and to give guidance for the appropriate use of these methods. The NACC found that evidence supports extracranial stimulation for facial pain, migraine, and scalp pain but is limited for intracranial neuromodulation (Deer et al. 2014).

**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.

**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/pmn.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm). (Accessed March 24, 2016)

**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™ Quattrode® 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/pmn.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm). (Accessed March 21, 2016)

On March 11, 2014, the FDA approved marketing of Cefaly (STX-Med; Herstal, Belgium) as a preventative treatment for migraine headaches. This is the first transcutaneous electrical nerve stimulation (TENS) device authorized specifically for use prior to the onset of pain. Additional information is available at: [http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm388765.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm388765.htm). (Accessed March 21, 2016)

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.

**REFERENCES**
The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2016T0080S]


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