Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache) (for Louisiana Only)

Policy Number: CS086LA.~~S~~**T**
Effective Date: ~~December 1, 2022~~**TBD**

➲ Instructions for Use

Table of Contents **Page**

Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

The following are proven and medically necessary for treating pain due to malignancy involving the head and neck:

- Injection of local anesthetics and/or steroids used as greater occipital nerve blocks
- Occipital nerve ablation (destruction by neurolytic agent)

The following are unproven and not medically necessary for diagnosing and/or treating occipital neuralgia or headaches including migraine and Cervicogenic Headaches, due to insufficient evidence of efficacy:

- Injection of local anesthetics and/or steroids, used as greater occipital nerve blocks
- Neurostimulation or electrical stimulation
- Occipital **Neurectomy**
- Partial posterior intradural C1-C3 **Rhizotomy**
- Radiofrequency ablation (thermal or pulsed) or denervation
- Rhizotomy of C1-C3 spinal dorsal roots
- Surgical decompression of second cervical nerve root and ganglion
- Surgical decompression of the greater occipital nerve

Definitions

Cervicogenic Headache: Referred pain perceived in the head from a source in the neck. In the case of C~~c~~ervicogenic H~~h~~eadache, the cause is a disorder of the cervical spine and its component bony, disc and/or soft tissue elements. (American Migraine Foundation, 2016)

Neurectomy: Partial or total excision or resection of a nerve. (Taber's Medical Dictionary)

Rhizotomy: Surgical section of a nerve root to relieve pain. (Taber's Medical Dictionary)

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 federal, state or contractual requirements 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 and **Guidelines** may apply.

CPT Code	Description
63185	Laminectomy with rhizotomy; 1 or 2 segments
63190	Laminectomy with rhizotomy; more than 2 segments
64405	Injection(s), anesthetic agent(s) and/or steroid; greater occipital nerve
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
*64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64568	Open implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
64570	Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
64575	Open 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

CPT Code	Description
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

HCPCS Code	Description
*K1023	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm
*L8679	Implantable neurostimulator, pulse generator, any type
*L8680	Implantable neurostimulator electrode, each
*L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension

Diagnosis Code	Description
C76.0	Malignant neoplasm of head, face and neck
G89.3	Neoplasm related pain (acute) (chronic)

Codes labeled with an asterisk(*) are not on the state of Louisiana Fee Schedule and therefore **may** not **be** covered by the **s**~~S~~tate of Louisiana Medicaid Program.

Description of Services

Cervicogenic ~~h~~**H**eadache 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 **C**~~c~~ervicogenic **H**~~h~~eadache and occipital neuralgia. Oral analgesics and anti-inflammatory agents are effective for some **individual** ~~patient~~s, but there is a population of ~~patients~~ **individuals** 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, **R**~~r~~hizotomy, 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 **three** ~~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

Greater Occipital Nerve Blocks (GONB), Diagnostic and Therapeutic

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

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

Refer to the following website for diagnostic criteria for cervicogenic headache and **ON**~~occipital neuralgia~~: The International Classification of Headache Disorders, 3rd edition. Available at: http://www.ihs-headache.org/ichd-guidelines. (~~Accessed March~~**Accessed March 09, 2023**~~April 21, 2022~~)

In 2023, Hayes produced an Evidence Analysis Research Brief on Local Injection Therapy for Cervicogenic Headache and ON. According to the brief, which summarized the most recent evidence, there are published studies on local injection therapy for cervicogenic headache and ON. The new evidence consisted of systematic reviews with and without meta-analysis. Furthermore, there were no randomized controlled trials (RCTs), studies evaluating the therapy, or studies evaluating treatment guided by the therapy. Lastly, the brief concluded that there were no position statements or guidelines for the treatment, showing that the lack of available guidance appears to confer with no or unclear support for local injection therapy.

In a 2023 randomized, double-blind, placebo-controlled study, Chowdhury and associates explored the use of greater occipital nerve blockade for preventing chronic migraine. The trial consisted of a baseline period of four weeks. Participants with chronic migraine were randomly assigned 1:1 with placebo. The participants obtained four-weekly bilateral greater occipital nerve blockades with either 2 ml of 2% (40 mg) lidocaine (active group

n=22) or 2 ml of 0.9% saline (placebo n=22) injections for 12 weeks. The primary endpoint was the change from baseline across weeks 9-12 in the average number of headaches and migraine days. The key secondary endpoint was achieving a 50% reduction in headache days compared to baseline across weeks 9-12. Documenting and reporting serious adverse events were conducted to evaluate safety. The average headache and migraine days at baseline (±SD) were 23.4±4.4 and 15.6±5.7 days in the active group and 22.6 ±5.0 and 14.6 ±4.6 days in the placebo group, respectively. The active group had a considerable gain in least-squares mean reduction in the number of headaches and migraine days when compared to the placebo (-4.2 days [95% CI: -7.5 to -0.8; p =0.018] and -4.7 days [95%CI: 7.7 to 1.7; p = 0.003], in that order). In the active group, 40.9% of individuals reached a ≥ 50% reduction in headache days versus 9.1% of those receiving a placebo (p = 0.024). There were 64 mild and transient adverse events recorded from 16 individuals in the active group and 15 in the placebo group, and no death or serious adverse events were reported. Four-weekly greater occipital nerve blockade with 2% lidocaine for 12 weeks was superior to placebo in reducing the average number of headaches and migraine days for individuals with chronic migraine and a good tolerability profile. The study does not represent individuals with a chronic migraine history of 2-4 preventive treatment failures, which limits the generalizability of study results. More robust trials with longer follow up are necessary to decide whether to use greater occipital nerve blockade to prevent chronic migraines.

In a 2022 systematic review with meta-analysis, Velásquez-Rimachi and colleagues evaluated evidence and quality assessment of GONB local anesthetic combined or not with corticosteroids to prevent chronic migraine. The authors measured efficacy by assessing the change from baseline in the intensity and frequency of headaches in the intervention group compared to the placebo at a one-time point. The meta-analysis was performed with random effect models and evaluated random errors with the trial-sequential analysis (TSA), the risk of bias (ROB) with the ROB2 tool, and the certainty of the evidence with Grading of Recommendations, Assessment, Development, and Evaluations (GRADE). The review uncovered 2864 studies that showed GONB reduced the intensity of headaches at the end of the first month (migraine days [MD]: -1.35, 95% CI: -2.12 to -0.59) and the second month (MD: -2.10, CI 95%: -2.94 to -1.26) as well as the frequency of headaches (first month: MD: -4.45 days, 95% CI: -6.56 to -2.34 days; second month: MD: -5.49, 95% CI -8.94 to -2.03 days). Corticosteroids did not show a significant decrease in the frequency of headaches during the first month of treatment (MD: -1.1 days, 95% CI: -4.1 to 1.8, p = .45). Adverse events between the groups were similar, and the exploratory TSA demonstrated inconclusive results. The authors concluded that the limited evidence shows that GONB with local anesthetics can reduce the frequency and intensity of headaches compared to a placebo and adding corticosteroids did not demonstrate any additional benefits. However, the quality of the evidence was deficient because of the substantial ROB and imprecision. Additionally, considering the TSA was inconclusive, more extensive, more specific trials are necessary.

Malekian et al. (2022) conducted a randomized, double-blind, placebo-controlled trial; individuals suffering from episodic migraines without aura were randomized to triamcinolone or lidocaine, triamcinolone plus lidocaine, or saline groups. Individuals were evaluated at baseline, one week, two weeks, and four weeks after the injection. All 55 participants who completed the study were assessed for severity, duration of headaches, and side effects. In all four groups, the ANOVA measures revealed that the severity and duration reduced considerably after the greater occipital block ($P < 0.001$, $P = 0.001$, respectively). No difference was shown amongst groups at any point during the study ($P > 0.05$). A considerable decrease in frequency compared to baseline ($P = 0.002$, P

= 0.019) was noted for groups two2 and three3 with lidocaine as part of the injection in paired sample T-test. Reported side effects with an association with triamcinolone were seen in three participants. The authors concluded that greater occipital block with a local anesthetic reduces the number of attacks in episodic migraine. No injection was better than the placebo regarding the duration and severity of the headaches. The trial uncovered that all four types of injections used effectively decreased the severity and the duration of headaches in episodic migraines, and no block solution was better than the 0.9% saline solution as a placebo at any of the time points. The trial uncovered a significant decrease in headaches for individuals receiving lidocaine alone or combined with triamcinolone compared to 0.9% saline injection or triamcinolone. Further studies exploring whether these results were caused by the compressive effect of injected solutionsolution, or the placebo effect are necessary.

Hasırcı Bayır et al. (2022) conducted a retrospective review of patient records to examine the efficacy of greater occipital nerve block (GONB) in adult patients with primary headaches. The study included 53 participants from a single center outpatient clinic who presented with episodic migraine **(EM)** (n = 36), tension-type headache (n = 12), chronic migraine (n = 4), or cluster headache (n = 1) and who completed a **three**-3-month follow-up visit. The study population was predominately female (86.79%), with a median age of 43.06 years. The participants underwent evaluation before and after receiving a GONB for headache type, attack duration, attack frequency, **the** severity of pain, and analgesic intake. Their initial values were then compared with the follow-up values at months **months one, three, and six**1, 3, and 6. The participants underwent GONB once a week for **three** 3 weeks then once a month if they reported a decrease in the duration, severity, or frequency of headache for a maximum of **six** 6 months based on their clinical responses. The authors reported that the migraine group showed a statistically significant decrease in Visual Analog Scale (VAS) scores, attack duration, the mean value of monthly number of attacks and analgesics taken at 6 months compared to their initial scores. Participants in the tension-type headache group showed a statistically significant decrease in their VAS scores, attack durations, mean value of the monthly number of attacks, and analgesics taken compared to their initial scores at the end of the **three** 3 month follow-up. The values for the tension-type headache group at **six** 6 months were statistically not significant as only 2 **two** of the 12 participants completed the **six** 6-month follow-up. Limitations of the study include the small sizes of each headache type, the preponderance of female participants, the use of various concomitant medications during the trial by some participants, and the study design. The authors concluded that repetitive GONB is an effective treatment method for migraine and tension-type headache**s**.

In a meta-analysis aimed at evaluating the therapeutic effectiveness of greater occipital nerve block (GONB) against post-dural puncture headache (PDPH), Chang et al. (2021) reviewed 7 **seven** studies (**four** 4 RCTs and 3 **three** non-RCTs) to determine the severity of pain at 24 hours post-procedure. **The authors defined intervention failure** Intervention failure was defined by the authors as repeated GONBs, the use of analgesics, or the need for an epidural blood patch. Secondary outcomes analyzed in this study included the impact of GONB on pain relief at **one** 1 hour and at 12 hours post-procedure. Their meta-analysis included 275 adult **individuals,** patients and the sample sizes of the included studies ranged from 16 to 90 **participants** patients. The authors found a moderate **ROB** risk of bias among the non-RCT studies overall. They reported that the pooled results showed a lower mean pain score at 24hours **and** as well as at **one**1 hour and 12 hours post-procedure. The analysis also showed that **using** the use of GONB also decreased the risk of intervention failure. Limitations noted by the authors included high heterogeneity among

the study populations, the difference in treatment provided to the control groups (placebo, bed rest, hydration, oral analgesics), the small number of RCTs available for analysis, and the short-term follow-up of 24 hours. The authors concluded that their meta-analysis showed that GONB has a therapeutic effect up to 24 hours post-procedure against PDPH with a low risk of intervention failure. They recommended further large-scale studies to evaluate the its therapeutic benefit of GONB beyond the acute phase of PDPH.

Caponnetto et al. (2021) conducted a systematic review to summarize the effectiveness and safety of GONBs in treating cervicogenic headaches. (CGH). The authors included seven studies, 5 five observational studies, and two 2 non- RCTs randomized controlled trials with a total of 140 participants were included. Follow-ups for outcomes evaluation varied among the studies, ranging from 5 minutes to 9 months after the procedure. Pain intensity was evaluated through the Visual Analogue Scale (VAS) or the Numeric Pain Rating Scale (NPRS). The m Monthly mean frequency of pain was 27 days at baseline and changed to 3.2 after one 1 week, 2.4 after two 2 weeks, 3.6 after 1.5 months, and 2.3 after 3.5 months. In 5 five studies, mean pain reduction ranged from 8.2 (at two 2 weeks after the first block) to -0.1 (at one 1 month after the third block). Three studies reported minor adverse events. The authors concluded that the limited available evidence suggested that GONBs effectively improve pain in patients with cervicogenic headache CGH, both as acute and as a preventative treatment. The available studies were either observational, non-controlled studies, or non-randomized trials, with a low-level of evidence. Larger and randomized studies are needed to confirm the efficacy of the procedure. (Author Lauretti et al. [(2014],) which was previously cited in this policy, is included in this study).

Friedman et al. (2020) conducted an RCT randomized controlled trial to determine whether GONB was as effective as intravenous (IV) metoclopramide for migraine. A double-dummy, double-blind, parallel-arm, non-inferiority study was conducted in 2 two emergency departments (EDs). Individuals Patients with migraine of moderate or severe intensity migraines were randomized to receive bilateral GONB, with each side administered 3 mL of bupivacaine 0.5% or metoclopramide 10 mg IV. The primary outcome was improvement in pain on a 0-10 scale between time 0 and 1 hour later. Secondary outcomes included sustained headache relief, defined as achieving and maintaining for 48 hours a headache level of mild or none without the use of additional analgesic medication, and the use of rescue medication in the ED. Over a 2.5-year study period, 99 participants patients were randomized, 51 to GONB and 48 to metoclopramide. Patients Those who received the GONB reported a mean improvement of 5.0, and those who received metoclopramide reported a mean improvement of 6.1. Sustained headache relief was reported by 11/51 (22%) GONB and 18/47 (38%) metoclopramide patients. Of the 51 individuals with GONB patients, 17 (33%) required rescue medication in the ED vs. 8/48 (17%) metoclopramide patients. An adverse event was reported by 16/51 (31%) GONB patients and 18/48 (38%) metoclopramide patients. The authors concluded that GONB with bupivacaine was less efficacious than not as efficacious as IV metoclopramide for the first-line treatment of migraine in the ED.

A 2019 Hayes Health Technology Assessment report focused on the efficacy and safety of GONB greater occipital nerve block (GONB) for the preventive treatment of chronic migraine (CM) headaches for individuals in patients with an inadequate response to standard care. An updated literature search was performed by Hayes in October 2021 that found 1 newly published study that met the inclusion criteria; however, the data did not result in a change to their report recommendations. The overall quality of the body of evidence remained rated as low due to individual study limitations, some inconsistencies in outcomes, and imprecision in some comparisons or outcomes examined in only a few studies or a single study. GONB with an injection of a local anesthetic is relatively

safe and may improve most headache outcomes over the short term compared with placebo. Little to no evidence meeting inclusion criteria was found around benefit of chronic use of this therapy. There is a need for additional, larger, well-designed controlled trials with longer follow-up to adequately determine the optimal clinical role of GONB in the preventive treatment of **chronic migraine** ~~CM~~. There was small or insufficient evidence for the use of GONB for the prevention of debilitating symptoms of ~~episodic migraine (~~EM~~)~~ or transformed migraine in adult**s** ~~patients~~ who do not respond adequately to standard therapy**. An updated literature search was performed by Hayes in October 2021 that found one newly published study that met the inclusion criteria; however, the data did not result in a change to their report recommendations. The overall quality of the body of evidence remained rated as low due to individual study limitations, some inconsistencies in outcomes, and imprecision in some comparisons or outcomes examined in only a few studies or a single study. In the 2022 annual review, an updated literature search was performed by Hayes, uncovering one newly published study meeting the inclusion criteria. Hayes did not change their rating, which is based on low-quality evidence that suggests GONB with an injection of a local anesthetic is relatively safe and could improve most headache outcomes over the short term when compared to placebo. The low rating reflects the heterogeneity in the patient populations, and varying treatment protocols across studies. Additionally, there is little to no evidence that meets the inclusion criteria that found a benefit for chronic therapy use. The review again concluded that there is a need for added, well-designed controlled trials that have a longer follow-up to determine the optimal clinical role of GONB for preventing chronic migraines. Similarly, for the use of GONB in preventing debilitating symptoms of EM or transformed migraine in adults who do not respond to standard therapy, the review rating remained low based on the paucity of evidence on these types of migraines** (Hayes, 2019b, updated 2022~~1~~).

A systematic review and meta-analysis were conducted by Shauly et al. (2019) to determine the efficacy of **GONB** ~~greater occipital nerve block~~ in the treatment of chronic migraine headaches. Nine studies were analyzed that reported mean number of headache days per month in both intervention and control groups. The study included 440 participants (intervention, n = 224; control, n = 216). Six of the included **RCTs** ~~randomized controlled trials~~ reported intervention treatment as either bupivacaine or lidocaine versus saline injection. Three of the included **RCTs** ~~randomized controlled trials~~ reported intervention treatment as corticosteroid in addition to bupivacaine or lidocaine versus bupivacaine or lidocaine with saline as the control group. Eight of the studies that were analyzed reported the mean headache days per month in both intervention and control groups. A total of 417 **individuals** ~~patients~~ were studied, with a pooled mean difference of −3.6 headache days (95 percent CI, −1.39 to −5.81 headache days; p < 0.00001). Pooled mean difference in pain scores of -2.2 (95 percent CI, -1.56 to -2.84) also demonstrated a decrease in headache severity compared with controls (p < 0.0121). Seven of the studies assessed reported mean **VAS** ~~visual analogue scale~~ pain scores. Pooled mean difference in pain scores of −2.2 (95 percent CI, −1.56 to −2.84; p = 0.0121). Two studies also reported patients that experienced a greater than 50 percent reduction in headache frequency. Risk ratios were calculated in these two studies, and the average risk ratio was found to be 0.76 (95 percent CI, 0.97 to 0.55; p < 0.00001). The authors concluded that greater occipital nerve blocking should be recommended for use in migraine patients, particularly those that may require future surgical intervention. The block may act as steppingstone for patients experiencing migraine headache because of its usefulness for potentially assessing surgical candidates for nerve decompression. The included studies had some limitations. For one, ~~patients~~ **those** in the control group in three of these studies were also given bupivacaine or lidocaine, whereas the intervention included corticosteroids. Variations between the control and intervention groups may skew the results of the meta-analysis. Another limitation of this study is the quality of included

studies. Most of the included studies exhibited a relatively small sample population. Clinical trials with a much larger sample population and longer period of observation should be conducted.

Özer ~~Ozer~~ et al. (2019) performed a study aimed to evaluate the efficacy of ~~greater occipital nerve (~~GON~~)~~ and supraorbital nerve (SON) blockade with local anesthetics for the preventive treatment of migraine without aura. Eighty-seven **individuals** ~~patients~~ diagnosed with migraine without aura **(MWOA)** were included in the study and randomly divided. One group was injected with 1% lidocaine; the other group was injected with 0.9% saline. GON and SON injections were done bilaterally. The injections were repeated weekly for **three** ~~3~~ weeks. ~~Patients~~ **Participants** were followed up for **two** ~~2~~ months to assess clinical response. Seventy-one **participants** ~~patients~~ completed the study. After **two** ~~2~~ months, the number of headache days decreased from 12.8 ±10.9 to 5.3 ±7.4, and VAS decreased from 8.3 ±1.0 to 5.5 ±1.9 in the blockade group. The number of headache days decreased from 12.4 ±10.3 to 7.5 ±7.2**,** and VAS decreased from 8.2 ±1.1 to 7.4 ±1.3 in the placebo group. Response was seen in 65.1% of the patients in the blockade group (65.4% for episodic migraine, 64.7% for chronic migraine) and 28.6% ~~of the patients~~ in the placebo group. The authors reported that the results suggest that GON and SON blockade with lidocaine was more effective than the placebo in the prophylactic treatment of both episodic and chronic migraine.

A retrospective study was performed by **Gönen** ~~Gonen~~ et al. (2019)**,** which included 51 ~~patients~~ **individuals** with episodic and chronic **cluster headache** ~~CH~~ that underwent ~~greater occipital nerve (~~ **greater occipital nerve blockade** ~~GON) blockade~~ with a single dose of rapid and long-acting steroid injection without additional prophylactic treatment. Pain assessment was performed using the ~~Visual Analog Scale (~~VAS~~)~~. The ~~patients~~ **participants** were asked to keep a record of the frequency, severity, and duration of attacks after **greater occipital nerve blockade** ~~GON blockade~~. In 28 (54.9%) ~~–~~**individuals** ~~patients~~, no attack occurred after **greater occipital nerve blockade**~~GON blockade~~**,** and cluster bouts were halted. Mean duration of attacks was 86.67 ±37.45 min before the treatment. In the 23 ~~patients~~ **individuals** that had at least one attack after **greater occipital nerve blockade**~~GON blockade~~, the mean duration of attacks was 31.73 ±36.10 min between post-treatment days 0-3, 29.35 ±40.49 min between post-treatment days 4-10, 28.48 ±42.17 min between post-treatment days 11-28, and 35.65 ±46.55 min after the post-treatment day 28 ($p < 0.001$). Between post-treatment days 0-3, the VAS score was 0 in 70.6% (n = 36), between 1 and 5 in 13.7% (n = 7), and between 6 and 10 in 15.7% (n = 8) of the **participants** ~~patients~~. Between post-treatment days 4-10, the VAS score was 0 in 76.5% (n = 39), between 1 and 5 in 7.8% (n = 4), and between 6 and 10 in 15.7% (n = 8) of the patients. Between post-treatment days 11-28, the VAS score was 0 in 80.4% (n = 41), between 1 and 5 in 3.9% (n = 2), and between 6 and 10 in 15.7% (n = 8) of the **individuals** ~~patients~~. After the post-treatment day 28, the VAS score was 0 in 86.3% (n = 44) and between 6 and 10 in 13.7% (n = 7) of the~~–~~ **participants** ~~patients~~. The authors concluded that **greater occipital nerve blockade** ~~GON blockade~~ is a practical, reliable, and cost-effective treatment option for ~~patients~~ **individuals** with episodic and chronic **cluster headache** ~~CH~~. The study is limited by its retrospective observations and small sample size.

A systematic review and meta-analysis were conducted by Zhang et al. (2018) to investigate the impact of **GONB** ~~greater occipital nerve (GON) block~~ on pain management of migraine. Seven **RCTs** ~~randomized controlled trials (RCTs)~~ (n-323) assessing the efficacy of GON**B** ~~block~~ versus placebo for migraine were included. The primary outcome was pain intensity. The authors concluded that ~~compared with control intervention in migraine~~

~~patients, GON~~**B** ~~block~~ intervention can significantly reduce pain intensity and analgesic medication consumption but has no remarkable impact on headache duration and adverse events **compared with control intervention for individuals with a migraine**. The analysis was based on only seven RCTs, with relatively small sample size (n < 100) and short follow-up time.

A prospective-randomized controlled study was conducted by Korucu et al. (2018) to evaluate the effectiveness of a greater occipital nerve ~~(GON)~~ blockade against a placebo and classical treatments (non-steroidal anti-inflammatory drugs and metoclopramide) among patients who were admitted to the ~~emergency department (~~ED~~)~~ with acute migraine headaches. Sixty **participants** ~~patients~~ were randomly assigned to ~~3~~ **three** treatment groups: the **greater occipital nerve blockade** ~~GON blockade~~ group (nerve blockade with bupivacaine), the placebo group (injection of normal saline into the GON area), and the ~~intravenous (~~IV~~)~~ treatment group (IV dexketoprofen and metoclopramide). The pain severity was assessed at 5, 15, 30, and 45-minutes with a 10-point pain scale score (PSS). The mean decreases in the 5-, 15-, 30-, and 45-minutes PSS scores were **more significant** ~~greater~~ in the **greater occipital nerve blockade** ~~GON blockade~~ group than in the dexketoprofen and placebo groups. The authors concluded that a **greater occipital nerve blockade** ~~GON blockade~~ was as effective as an IV dexketoprofen + metoclopramide treatment and superior to a placebo ~~in patients~~ **for individuals** with acute migraine headaches. No follow-up was noted.

~~Allen et al. (2018) [WRM2]performed a retrospective cohort study to assess the efficacy of greater occipital nerve (GON) block in acute treatment of migraine headache, with a focus on pain relief. The study was undertaken between January 2009 and August 2014 and included patients who underwent at least 1 GON block and attended at least 1 follow-up appointment. Change in the 11-point numeric pain rating scale (NPRS) was used to assess the response to GON block. Response was defined as "minimal" (< 30% NPRS point reduction), "moderate" (31-50% NPRS point reduction), or "significant" (> 50% NPRS point reduction). A total of 562 patients met inclusion criteria. Of these 562, 459 patients (82%) rated their response to GON block as moderate or significant. No statistically significant relationship existed between previous treatment regimens and response to GON block. GON block was equally effective across the different age and sex groups. The authors concluded that greater occipital block seems to be an effective option for acute management of migraine headache, with promising reductions in pain scores.~~

~~A Hayes September 2017 report for the use of anesthetic-based injections for individuals with cervicogenic headache found overall low-quality body of evidence suggesting that anesthetic-based injections provide superior pain relief compared with placebo and similar pain relief compared with more invasive treatments. The report was updated on November 15, 2021 although Hayes found no newly published studies that met the inclusion criteria set out in their report. The report continues to conclude that there remains uncertainty regarding the duration of pain relief, the optimal formulation of anesthetic-based injections, the comparative effectiveness and safety versus conservative treatments, and patient selection criteria. For the use of anesthetic-based injections in patients with occipital neuralgia, the report found very-low-quality body of evidence suggesting that anesthetics plus steroid injections provide inferior pain relief compared with more invasive treatments (Hayes 2017, updated 2021).~~

Tang et al. (2017) conducted a systematic review and meta-analysis to explore the efficacy of ~~greater occipital nerve (~~GON**B**~~) block~~ in migraine patients. Six ~~randomized controlled trials (~~RCTs~~)~~ assessing the efficacy of GON**B** ~~block~~ versus placebo in migraine patients were included. Compared with control intervention in migraine patients, GON**B**

~~block~~ intervention was found to significantly reduce pain score, number of headache days, and medication consumption but demonstrated no influence on duration of headache per four weeks. The authors concluded that GON block intervention can significantly alleviate pain, reduce the number of headache days and medication consumption, but have no significant influence on the duration of headache per four weeks for migraine patients. The short-term follow-up did not allow for assessment of intermediate and long-term outcomes.

Gul et al. (2017) evaluated the efficacy of greater occipital nerve ~~(GON)~~ blockade **for individuals** ~~in patients~~ with chronic migraine ~~(CM)~~ in randomized control study. The study included 44 **individuals with chronic migraine** ~~CM patients~~ who were randomly divided onto two ~~groups;~~ **groups:** group A (bupivacaine) and group B (placebo). **greater occipital nerve blockade** ~~GON blockade~~ was administered four times (once per week) with bupivacaine or saline. After **four**~~4~~ weeks of treatment, patients were followed up for **three** ~~3~~ months, and findings were recorded once every month for comparing each month's values with the pretreatment values. The primary endpoint was the difference in the frequency of headache (headache days/month). The ~~Visual Analogue Scale (~~VAS~~)~~ pain scores were also recorded. No severe adverse effects were reported. Group A showed a significant decrease in the frequency of headache and VAS scores at the first, second, and third months of follow-up. Group B showed a significant decrease in the frequency of headache and VAS scores at the first month of follow-up, but second and third months of follow-up showed no significant difference. The authors concluded that their results suggest that **greater occipital nerve blockade** ~~GON blockade~~ with bupivacaine was superior to placebo, has long-lasting effect than placebo, and was found to be effective for the treatment of **chronic migraine** ~~CM~~. More studies are needed to better define the safety and cost-effectiveness of **greater occipital nerve blockade** ~~GON blockade~~ in chronic migraine.

Cuadrado et al. (2017) assessed the short-term clinical efficacy of ~~greater occipital nerve (~~GON~~)~~ anesthetic blocks in chronic migraine ~~(CM)~~ in a double-blind, randomized, placebo-controlled clinical trial. Thirty-six women with **chronic migraine** ~~CM~~ were treated either with bilateral GON block with bupivacaine 0.5% (n = 18) or a sham procedure with normal saline (n = 18). Headache frequency was recorded a week after and before the procedure. Pressure pain thresholds (PPTs) were measured in cephalic points (supraorbital, infraorbital, and mental nerves) and extracephalic points (hand, leg) just before the injection (T0), one hour later (T1) and one week later (T2). Anesthetic block was superior to placebo in reducing the number of days per week with moderate-or-severe headache, or any headache. Overall, PPTs increased after anesthetic block and decreased after placebo; after the intervention, PPT differences between baseline and T1/T2 among groups were statistically significant for the supraorbital and infraorbital sites. The authors concluded that GON anesthetic blocks appear to be effective in the short term in **chronic migraine** ~~CM~~, as measured by a reduction in the number of days with moderate-to-severe headache or any headache during the week following injection. This study was limited by its heterogeneous patient population and small sample size.

A systematic review was conducted by Yang et al. (2016) to evaluate the clinical efficacy and safety of occipital nerve stimulation (ONS) for treating migraine. Five **RCTs**~~randomized controlled trials~~, ~~4~~four retrospective studies, and one prospective study met the inclusion criteria. The authors concluded that results from the retrospective studies and case series indicated that ONS significantly reduced the pain intensity and the number of days with headache in patients with migraine. The evidence of ONS efficacy established by **RCTs** ~~randomized controlled trials~~ was limited. Improvement was noted in the migraine disability assessment (MIDAS) score and SF-36 score at follow-up. The mean complication incidence of ONS was 66% for the reviewed studies. The authors recommended

that future clinical studies should optimize and standardize the ONS intervention process and identify the relationship among the surgical process, efficacy, and complications resulting from the procedure.

~~Okmen et al. (2016) [WRM3]evaluated six months of results from repeated GONBs. greater occipital nerve blocks (GON). A standard 2 mL of 0.5% Bupivacaine GON blockage once a week for four4 weeks was applied. The Visual Analog Scale (VAS) scores, the number of migraine attacks, and the Migraine Disability Assessment Questionnaire (MIDAS) scores were reported. The participants patients were not allowed to use medication for prophylaxis, and Ibuprofen was prescribed for any migraine attacks. The initial mean number of attacks per month before starting treatment was 8.33 + 2.31. After treatment, the initial MIDAS mean was found to be 2.82 per month, this declined to 1.47 in 3rd and was 1.50 in the 6th month. The mean VAS scores were recorded as follows for each month: 6.28 ±1.24, 3.13 ±0.97, 2.55 ±1.19, 2.35 ±1.26, 2.38 ±1.20 and 2.48±1.30, respectively. This difference was noted to be statistically significant. The authors concluded that GON blockage with 2mL of 0.5% Bupivacaine can be a supportive treatment in migraine treatment, with no serious adverse effects reported. This is an uncontrolled study with a small sample size.~~

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.

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 **for individuals** ~~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 **individuals,** ~~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. **Individuals** ~~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)~~ **for** ~~in~~ 84 **individuals** ~~patients~~ with chronic migraine at **one, two, and three** ~~1-, 2-, and 3~~-month follow-ups. **Participants** ~~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 **four** ~~4~~ weeks. After **four** ~~4~~ weeks, the study was unblinded and patients in the placebo group were crossed over to GONB with bupivacaine once per week for **eight** ~~8~~ weeks. Patients in the intervention group were followed for **four** ~~4~~ weeks, and GONB was repeated with bupivacaine. After **one** ~~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 **two** ~~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 **three** ~~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 **three** ~~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.

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 (> **one** ~~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 **individuals** ~~patients~~ received placebo treatment. Because of missing data, the full analysis of 33 **individuals** ~~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~~ **and** **two** ~~2~~ weeks, **one** ~~1~~ month, and **two** ~~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 **two** ~~2~~, **four** ~~4~~, and **eight** ~~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 regimens 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 **GONBs** ~~greater occipital nerve blocks~~ may be an effective treatment for **individuals** ~~patients~~ with migraine post-concussive~~,~~ or other headaches; however, these studies had small sample sizes or did not have control groups (Niraj, 2014; Govindappagari, 2014; Seeger, 2014; Guerrero, 2012~~;)~~**;)**. 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.

Lambru et al. (2014) prospectively assessed the efficacy and consistency of response to greater occipital nerve blockade ~~(GONB)~~ in a series of 83 **individuals with** chronic cluster headache **chronic cluster headache** ~~(CCH) patients~~. After the first GONB, a positive response was observed in 47 (57%) ~~-~~ **participants** ~~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 **for individuals with chronic cluster headache** ~~in CCH patients~~. According to the authors, when performed three times monthly, GONB may have a useful role in the management of **chronic cluster headache** ~~CCH~~. The lack of a control group limits the validity of the results of this study.

~~Weibelt et al. (2010) evaluated the safety and efficacy of occipital nerve blocks (ONBs) used to treat cervicogenic chronic~~ [WRM4] ~~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.~~

~~Ashkenazi et al. (2010)~~ [WRM5] ~~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~~ **~~GONB~~** ~~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.~~

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 **ON** ~~occipital neuralgia~~ and cervicogenic headache.

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

Goyal et al. (2022) performed a systematic review to evaluate various interventional treatment for cervicogenic headache ~~(CeH)~~ and compare their relative efficacies. The final analysis consisted of 23 articles published between January 2001 and March 2021. Eleven studies evaluated the effect of radiofrequency ablation (RFA)~~;~~ ~~5~~ **five** evaluated ~~occipital nerve blocks~~ **ONB**, ~~2~~ **two** for facet joint injections, **two** ~~2~~ for cervical epidural injection, and **two** ~~2~~ for cryoneurolysis. The ~~occipital nerve blocks~~**ONB** (GON, LON) showed only limited evidence, as most of the studies were non-controlled and yielded only transient benefits. Radiofrequency lesioning may be preferable over other interventions

because of its long duration of effect, better efficacy, and fewer side effects. Conventional RFA is neuro-destructive and is associated with high complication rates such as neuritis or deafferentation pain. The authors noted several limitations in their review including the lack of available RCTs, the structure, the heterogeneity of the inclusion/exclusion criteria and outcomes assessed among the studies, the small sample sizes and short follow-up periods in the studies and the flaws and inconsistencies in some of the study designs. Based on available literature, the authors concluded that ~~occipital nerve blocks~~**ONB** may be a reasonable option for **cervicogenic headache**~~CeH~~ treatment. Radiofrequency lesioning was found to be better with long-term positive outcomes, and pulsed therapy had better safety. However, the review revealed only limited evidence, and additional large, prospective, well-designed RCTs are needed to provide more concrete evidence and to establish relative efficacy of the various available interventions discussed for the management of **cervicogenic headache** ~~CeH~~.

A systematic review and meta-analysis to evaluate the proportion of **individuals with** migraine ~~patients~~ reporting elimination of migraine headache (MH) after migraine trigger site surgery and whether surgery compared to sham or no surgery is more effective in the elimination of MH was conducted by Vincent et al. (2019). A total number of 627 ~~patients~~ **participants** with a diagnosis of migraine in compliance with the classification of the International Headache Society **(IHS)** were included. The treatment consisted of one or more surgical procedures involving the extracranial nerves and/or arteries with outcome data available at minimum **six** ~~6~~ months. A proportion of 0.38 of ~~patients~~ **participants** (random effects model, 95% CI [0.30–0.46]) experienced elimination of migraine headaches at 6–12 months follow-up. Using data from three **RCTs** ~~randomized controlled trials~~, the calculated odds ratio for 90–100% elimination of migraine headaches is 21.46 (random effects model, 95% CI [5.64–81.58]) for **individuals** ~~patients~~ receiving migraine surgery compared to sham or no surgery. The authors reported that migraine surgery leads to elimination of migraine headaches in 38% of migraine patients. However, more elaborate randomized trials are needed with transparent reporting of patient selection, medication use, and surgical procedures and implementing detailed and longer follow-up times.

Gande et al. (2016) performed a retrospective chart review of 75 **individuals with** ~~occipital neuralgia (~~ON~~)~~ ~~patients~~ who underwent cervical dorsal root rhizotomy (CDR). Fifty-five patients were included who met the ~~International Headache Society's (~~IHS~~)~~ diagnostic criteria for ON, responded to CT-guided nerve blocks at the C-2 dorsal nerve root, and had at least one follow-up visit. Telephone interviews were additionally used to obtain data on patient satisfaction. The average follow-up was 67 months (range 5-150). Etiologies of ON included the following: idiopathic (44%), posttraumatic (27%), postsurgical (22%), post-cerebrovascular accident (4%), postherpetic (2%), and post-viral (2%). At last follow-up, 35 ~~patients~~ **participants** (64%) reported full pain relief, 11 (20%) partial relief, and **seven** ~~7~~ (16%) no pain relief. The extent of pain relief after CDR was not significantly associated with ON etiology. Of 37 ~~p~~~~atients~~ whose satisfaction-related data were obtained, 25 (68%) reported willingness to undergo repeat surgery for similar pain relief, while 11 (30%) reported no such willingness; a single patient (2%) did not answer this question. Twenty-one individuals (57%) reported that their activity level/functional state improved after surgery, **five** ~~5~~ (13%) reported a decline, and 11 (30%) reported no difference. The most common acute postoperative complications were infections in 9% (n = 5) and CSF leaks in 5% (n = 3); chronic complications included neck pain/stiffness in 16% (n = 9) and upper-extremity symptoms in 5% (n = 3) such as trapezius weakness, shoulder pain, and arm ~~paresthesias~~ **paresthesia**. The authors concluded that **CDR** ~~cervical dorsal root rhizotomy~~ provides an efficacious means for pain relief in patients with medically refractory ON. In the appropriately

selected patient, it may lead to optimal outcomes with a relatively low risk of complications. The study is limited by its retrospective observations.

Excision of intervertebral discs from the cervical spine with interbody fusion was evaluated in two prospective case series by the same authors. **For individuals** ~~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 participants** ~~patients~~, immediate pain reduction was followed by recurrences starting at **two**~~2~~ months after surgery (Jansen **&** ~~and~~ Sjaastad, 2006). **For individuals** ~~In patients~~ with unilateral cervicogenic headache, these same authors reported that ~~all patients~~**all patients** were generally pain- free during the **one to** ~~three1- to 3-month~~ **three month** period when the ~~patients~~ **individuals** wore cervical collars restricting movement, but only **five** ~~5~~ out of 32 **individuals** ~~patients~~ remained pain- free three3 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 **individuals** ~~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 **individuals** ~~patients~~ with unilateral and in 36% with bilateral **cervicogenic** ~~headacheCEH~~**headache (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). **The small sample size limits these conclusions** 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 **participants** ~~patients~~ with cervical disc prolapse who were prospectively followed for **three** ~~3~~ months. Data regarding headache and neck pain were collected prior to and **seven** ~~7~~ and 90 days after surgery for the disc prolapse. Fifty **individuals** ~~patients~~ with lumbar disc prolapse, matched for age and sex, undergoing surgery were recruited as controls. Twelve of 50 ~~patients~~ **individuals** with cervical disc prolapse reported new headache and neck pain. Seven **individuals** ~~patients~~ (58%) fulfilled the 2004 **IHS** ~~International Headache Society~~ criteria for cervicogenic headache. One week after surgery, 8/12 ~~patients~~ **individuals** with cervical disc prolapse and headache reported to be pain-–free. One **individual** ~~patient~~ was improved and three were unchanged. Three months after cervical prolapse surgery, seven **individuals** ~~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 **individuals** ~~patients~~ after surgery for the cervical disc prolapse. These findings require confirmation in a **more extensive** ~~larger~~ study.

Nerve Decompression and Occipital Neurectomy for Headaches

The available evidence is insufficient to conclude that occipital neurectomy or nerve decompression, including decompression of the supraorbital, supratrochlear, zygomaticotemporal, or **GONs** ~~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.

In a single-–center retrospective cohort study involving 154 **individuals** ~~patients~~ with recurrent migraine headaches lasting for over ~~2~~ **two** years, Chen et al. (2021) examined the feasibility of scalp (trigger areas) nerve decompression as a treatment for the

management of refractory chronic migraine (rCM). ~~(CM).~~ The authors divided the trigger areas according to the nerve compromised as frontal (supraorbital nerve), temporal (auriculotemporal nerve) or occipital (greater occipital nerve) as determined by the location that the patient identified as the headache start site or the most tender spot along the migraine headache zone. The study group included 91 (59.09%) patients (69 men and 85 women) with a mean age at treatment of 47 years who underwent auriculotemporal nerve decompression, 27 (13.63%) had ~~supraorbital nerve~~SON decompression, 15 (9.74%) had GON ~~greater occipital nerve~~ decompression, and the remaining 21 (13.63%) patients had more than one nerve decompression performed. Postoperative outcome was assessed by ~~2~~two neurosurgeons on days 1, 3, and 7, and at 6 months and one ~~1~~ year. The authors reported that 96 (62.2%) of individuals ~~patients~~ were considered cured at one ~~1~~-year follow-up or latest follow-up (complete resolution of initial symptoms and pain, and were free of postoperative discomfort), another 29 individuals ~~patients~~ (18.83%) reported improvement in their symptoms with decrease in the intensity and frequency of headaches more than 50% from the initial presentation and require no medication, 21 ~~patients~~ individuals (13.64%) had a partial symptomatic remission with a decrease in intensity and frequency of headaches of less than 50% and that required adjuvant medical treatment, and five people ~~5 patients~~ (3.25%) reported no change to their symptoms. Limitations noted by the authors included the retrospective nature of their study, the lack of control group, and the subjective nature of the questionnaire used to measure clinical outcome. The authors concluded that nerve decompression of trigger site areas (frontal, temporal and/or occipital) by removal of tissue, muscle and vessels ~~in patients~~ for individuals with medically rCM ~~refractory CM~~ is a feasible alternative treatment modality with a high success rate of up to 80.5%. They recommend future studies that include the use of a more detailed and objective post-procedural evaluation tool.

McNutt et al. (2020) conducted a systematic review of 12 articles (including Pisapia [~~(~~2012]~~)~~, Ducic et al. [~~(~~2009]~~)~~, Ducic et al. [~~(~~2014]~~)~~, Choi [~~(~~2015]~~)~~, Jose et al. [~~(~~2018]~~,)~~ and Li et al. [~~(~~2012]~~)~~ below) that directly addressed the question of neurolysis (NL) versus neurectomy (NR) for the treatment of ~~occipital neuralgia (~~ON~~)~~ after failure of conservative therapy to provide clarity regarding differences between the two approaches and a recommendation on the superiority of one treatment over the other. The articles included ~~7~~ seven observational studies and ~~5~~ five single case reports as no RCTs ~~randomized controlled trials~~ were identified in their literature search and all were found to be level IV, low-quality evidence so they were unable to complete a meta-analysis. There was a total of 473 participants ~~patients~~ in the analysis with follow-up between two~~2~~ months and 5.6 years. Their analysis showed that individuals ~~patients~~ had a positive outcome when they had a positive response to GONB ~~greater occipital nerve block~~ or Botox, tenderness over the GON ~~greater occipital nerve~~ and were under the care of a neurology specialist or pain specialist; however, the longer duration of the headache (greater than 13 years) and retro-orbital/frontal radiation were associated with treatment failure. The authors noted that the included studies utilized various inclusion and exclusion criteria as well as outcome measures. Other limitations they noted included the number of case reports, lack of comparison group in many studies, high dropout rates, small sample sizes, lack of blinding and a lack of correlating outcomes to a particular surgical treatment. After reviewing the data, the authors found there was conflicting results for NL and no consistent outcome identified for NR. They found that many patients had concomitant headache diagnoses and additional confabulators and they were not screened for other causes of occipital headache. The authors determined there was insufficient evidence to recommend one treatment method ~~method of treatment~~ over the other. The authors stated that higher-quality studies including RCTs are needed to evaluate these surgical options.

A systematic review and meta-analysis were conducted by Baldelli et al. (2020). The ~~9~~ **nine** selected studies included **seven** ~~7~~ retrospective studies (4 case-control; 3 case series), **one** ~~1~~ blinded randomized controlled clinical trial, and **one** ~~1~~ a prospective cohort study. A total of 1135 **individuals** ~~patients~~ were included in studies on occipital nerve decompression with different surgical techniques. The sample size of each study ranged from 11 to 476 ~~patients~~. Surgical outcome was measured with the migraine headache questionnaire, the percentage of postoperatively pain relief, and the migraine headache index (MHI). Follow-up was at least **six** ~~6~~ months in each study. General positive response after surgery (> 50% reduction in occipital migraine headaches) ranged from 80.0% to 94.9%. The authors concluded that success in occipital decompression surgery is high, surpassing 90% in several studies but other randomized clinical trials are necessary to definitively confirm the findings. A main limitation is the retrospective nature of most of the studies. (Authors Ducic et al. **[**~~(~~2009**]**~~)~~ and Guyuron et al. **[**~~(~~2009**],**~~)~~ which were previously cited in this policy, are included in this study).

Ambrosini and Schoenen (2016) performed a meta-analysis of studies assessing (minimally) invasive interventions targeting pericranial nerves that could be effective in refractory patients. These included nerve blocks/infiltrations, the percutaneous implantation of neurostimulators**,** and surgical decompression procedures. The authors concluded that the clinical implications for these treatments are as follows:

- Suboccipital infiltrations (or **GONBs**~~greater occipital nerve blocks~~) are effective, evidence-based, safe**,** and inexpensive treatments for short-term prophylaxis in cluster headache ~~patients;~~**patients,** while evidence for such an effect is weak in migraine.
- Percutaneous ~~occipital nerve stimulation (~~ONS~~)~~ has long-term efficacy in refractory chronic cluster headache, but it has frequent adverse effects, and a sham-controlled trial is not yet available.
- Surgical decompression of pericranial nerves **for individuals with** ~~in~~ migraine**s were** ~~patients was~~ reported to be superior to sham surgery in one study, and most case series are non-controlled and published by the same group. Further better-designed RCTs are needed before surgical decompressions can be recommended **to treat** ~~in the treatment of~~ selected **individuals with** migraine**s** ~~patients~~.

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 **MIDAS** ~~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 **individuals** ~~patients~~ underwent surgical deactivation of trigger site(s). Eighty-nine of 100 **participants** ~~patients~~ in the treatment group underwent surgery, and 79 were followed for **five** ~~5~~ years. Ten **individuals** ~~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 **individuals** ~~patients~~ was not statistically different. Sixty-one (88 percent) of 69 ~~patients~~ **participants** experienced a positive response to the surgery after **five** ~~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 **five** ~~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 **five** ~~5~~-year follow-up and patient-reported data may have introduced recall bias~~ in the study~~.

~~In an effort~~ [WRM6]~~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).~~

Radiofrequency Ablation

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

In 2022, Suer and colleagues conducted a systematic review evaluating RCTs of cervical facet joint pain and cervicogenic headaches to establish the current level of evidence for treating the etiologies of pain with RFA. The primary outcome measured was pain relief and duration of pain relief, with the secondary outcomes measured being function, sleep, mood, return to work, additional treatments, and complications. The exploration uncovered four RCTs with a low ROB. The primary outcome measure of pain relief and duration of relief demonstrating a successful relief ranging from 30% to 50%. Secondary outcomes such as function and psychological distress were variable for treatment relief, and no significant difference was noted between groups in two of the studies included. The authors concluded the efficacy of cervical facet RFA for treating chronic neck pain. The evaluation is limited due to variability in the population and heterogeneous treatment outcomes with follow-up intervals that do not allow for meta-analyses. Questions remain, and further research is warranted on this treatment.

A systematic review by Orhurhu et al. (2021) was performed to summarize available evidence behind ~~radiofrequency ablation (~~RFA~~)~~ for headache**s**, including pain outcome measures, secondary outcomes, and complications. A total of 18 studies composed of **six** ~~6 randomized controlled trials (~~RCTs~~)~~, **six** ~~6~~ prospective studies, and **six** ~~6~~ retrospective studies were included in the review. All the studies assessed pain improvement with RFA **for individuals** ~~in patients~~ with headache**s**. Most studies targeted the occipital nerve for treatment. Complications were mostly mild and self-limiting, including eyelid swelling, rash, superficial infection of the procedural site, and worsening of headache. The review discussed multiple studies that suggest the efficacy of RFA in the treatment of headaches. Outcomes varied based on the difference in approaches regarding continuous radiofrequency versus pulsed radiofrequency, temperature, and duration of administration. Most studies discussed in the review indicate a therapeutic benefit of RFA for headaches over a short-term period. The authors concluded that pain outcomes beyond one year are under-studied and further studies are needed to determine the long-term effects of RFA for headaches. Limitations included a large variability in definitions of trigeminal neuralgia, radiofrequency technique, and patient selection bias. There is a paucity of strong longitudinal RCTs and prospective studies.

A retrospective review by Guo et al. (2021) was performed to evaluate the effect of low-temperature plasma radiofrequency ablation (LTPRA) of the sphenopalatine ganglion (SPG) in treating chronic and episodic cluster headache ~~(CH)~~. A total of 76 patients treated using LTPRA between January 2015 and October 2017 were reviewed. Fifty ~~patients~~ **individuals** suffered from episodic CH and the remaining 26 ~~patients~~ from chronic **cluster headache** ~~CH~~. The primary outcomes were clinical improvement rate, defined as the percentage of partial and complete pain relief results at **one** ~~1~~ day, 12 months, and 24 months of follow-up after the operation. Clinical improvement rates were 92.3%, 92.3%, and 73.1% in chronic **cluster headache** ~~CH~~ and 73.1%, 84% and 68% in episodic CH at each follow-up time point, respectively. Three **individuals with** chronic **cluster headache** ~~CH patients~~ and ~~7~~ **seven individuals with** episodic CH ~~patients~~ showed no pain relief after the operation. Drooping eyelids were found in ~~2~~ **two** cases, one recovered at the **three** ~~3~~-month follow-up but another one did not in the 24-month follow-up. No serious complications occurred intraoperatively or postoperatively. The authors concluded that LTPRA can be considered an effective and alternative surgical modality in treating patients with chronic and episodic CH~~,~~ based on SPG block. Further research with **RCTs** ~~randomized controlled trials~~ is needed to validate these findings.

Robinson et al. (2021) conducted a systematic review to summarize the current state of surgical ON management. Twenty-two studies met the inclusion criteria with a total of 766 **individuals** ~~patients~~. Fifteen studies evaluated interventions on the GON and/or LON and ~~7~~ **seven** studies evaluated interventions on the C2 nerve root. Interventions included decompression, ablation (radiofrequency and cryoablation), and stimulation. The studies used patient-reported pain scores as an outcome metric. Other outcome metrics included complication rates, patient satisfaction, quality of life, and analgesic usage. **The a**~~A~~verage duration of follow-up ranged from 3 to 67 months. The authors found that GON decompression decreased mean ON pain intensity from 7.18 ±1.33 to 1.73 ±1.95. Studies that addressed ablation, including ~~radiofrequency ablation~~**RFA** and cryoablation found an overall success rate of 85%, with an average ~~visual analog scale (~~VAS~~)~~ score decreased from 7.4 ±1.7 to 2.9 ±1.7. The authors found that C2 ganglion decompression led to therapeutic success, as defined by > 50% reduction in patient-reported preoperative pain without analgesia use~~,~~ in 70% of **individuals** ~~patients~~ at 2.5-year follow-up. Cervical dorsal rhizotomy provided full pain relief in 64% ~~of individuals~~**of individuals** ~~patients~~, partial relief in 20%, and no relief in 16% at **the five** ~~5~~-year follow-up. The authors concluded that ON treatment identified peripheral nerve decompression, ablation, and stimulation as useful therapeutic options for medically refractory occipital pain. This study is limited by the low level of evidence and significant **ROB** ~~risk of bias~~ of most of the articles. (Authors Acar et al. **[**~~(~~2008**]**~~)~~, Blake et al. **[**~~(~~2019**]**~~)~~, Choi et al. **[**~~(~~2015**]**~~)~~, Ducic et al. **[**~~(~~2014**]**~~)~~, Gande et al. **[**~~(~~2016~~]~~~~)~~, Jose et al. [~~(~~2018~~]~~~~)~~. Keifer et al. **[**~~(~~2017**]**~~)~~, Li et al. **[**~~(~~2012~~]~~~~)~~, **and** Pisapia et al. **[**~~(~~2012**]**~~),~~ which were previously cited in this policy, are included in this study).

Lee et al. (2020) performed a retrospective chart review to evaluate the efficacy and complications of C2 dorsal root ganglion (DRG) pulsed ~~radiofrequency ablation (~~RFA~~)~~ for cervicogenic headache ~~(CEH)~~ and to identify factors related to the outcome of the procedure. Electronic medical records of consecutive patients who underwent C2 DRG block for **cervicogenic headache** ~~CEH~~ from January 2012 to May 2018 at a pain center were reviewed. Consequent C2 DRG pulsed RFA was performed for **individuals** ~~whosepatients in whom the headache~~whose headache recurred after an initial period of relief 24 hours after the C2 DRG block. A *successful outcome* was defined as at least 50% pain relief at six~~6~~ months after C2 DRG pulsed RFA. Fluoroscopy-guided C2 DRG block was performed in 114 patients. Forty-five ~~participantspatients received~~ **participants received** C2 DRG pulsed RFA and 40.0% among them (18/45, success group) had ≥ 50% pain relief after **six** ~~6~~ months.

There were no post-procedure complications throughout the study period. More patients in the success group than in the failure group had a definite positive response (≥ 50% pain relief) to a previous C2 DRG block (p < .001). The authors concluded that C2 DRG pulsed RFA may be an effective treatment for **individuals** ~~patients~~ with **cervicogenic headache,** ~~CEH,~~ particularly for **those** ~~patients~~ who have previously experienced definite pain reduction after C2 DRG block. The limitations of the study design and small number of patients preclude firm conclusions.

Grandhi et al. (2018) performed a systematic review to examine the use of ~~radiofrequency ablation (~~RFA~~)~~ and pulse radiofrequency ~~(PRF)~~ for the management of cervicogenic headache. ~~(CHA).~~ A review of the literature was conducted, and 10 studies met inclusion for review. The authors concluded that RFA and **pulse** ~~P~~RFA provided very limited benefit in the management of **cervicogenic headache** ~~CHA~~ and there **needs to be** ~~is no~~ high-quality RCT**s** and/or strong non-RCTs to support the use of these techniques, despite numerous case reports **demonstrating** ~~that had demonstrated~~ benefit.

Luo et al. (2018) prospectively investigated the long-term effects of ultrasound-guided percutaneous pulsed radiofrequency in the treatment of 22 refractory idiopathic supraorbital neuralgia patients. A reduction in the verbal pain numeric rating scale score of more than 50% was used as the standard of effectiveness. The effectiveness rates at different time points within ~~two~~2 ~~years~~ **two years** were calculated. After a single pulsed radiofrequency treatment **(PRFT)**, the effectiveness rate at **one** ~~1~~ and **three** ~~3~~ months was 77%, and the rates at **six** ~~6~~ months, **one** ~~1~~ year, and **two** ~~2~~ years were 73%, 6%, and 50%, respectively. Twenty-three percent of **individuals** ~~patients~~ experienced mild upper eyelid ecchymosis that gradually disappeared after approximately **two** ~~2~~ weeks. The authors concluded that the study demonstrated ~~that for patients with refractory idiopathic supraorbital neuralgia,~~ percutaneous pulsed radiofrequency may be a safe and effective treatment choice **for individuals with refractory idiopathic supraorbital neuralgia**. The findings of this study need to be validated by well-designed studies.

Fang et al. (2016) conducted a study to evaluate the efficacy and safety of a non-ablative computerized tomography-guided ~~pulsed radiofrequency treatment~~ **PRFT** of sphenopalatine ganglion in patients with refractory cluster headaches. Sixteen consecutive cluster headache patients who failed to respond to conservative therapy treated with ~~pulsed radiofrequency treatment (~~PRFT~~)~~ of sphenopalatine ganglion were analyzed. Eleven of 13 **individuals with** episodic cluster headaches (ECH) ~~patients~~ (85%) and one of three **individuals with** chronic cluster headaches ~~(CCH) patients~~ (33%) were completely relieved of the headache. Two ECH patients and two **individuals with chronic cluster headache** ~~CCH patients~~ showed no pain relief following the treatment. The mean time following PRFT for partial pain relief was 1.3 days (ranging from 1 to 3 days) and the mean time following PRFT for complete pain relief was 6.3 days (ranging from 1 to 20 days). All patients enrolled in this study showed no treatment-related side effects or complications. The authors concluded that patients with refractory **ECH** ~~episodic cluster headaches~~ were quickly, ~~effectively~~ **effectively,** and safely relieved from the cluster period after computerized tomography-guided ~~pulsed radiofrequency treatment~~ **PRFT** of sphenopalatine ganglion, suggesting that it may be a therapeutic option if conservative treatments fail. Large sample sizes and long-term follow-up research will be useful to evaluate the efficacy of PRFT **for individuals with chronic cluster headache** ~~in CCH patients~~.

Nagar et al. (2015) conducted a systematic review to investigate the clinical utility of radiofrequency ~~(RF)~~ neurotomy~~,~~ and pulsed ~~RF (P~~RF**A**~~) 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 **cervicogenic headache** ~~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~~five 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~~ **four** randomized trials among them 2/4 were of high quality, 3/4 investigated RF ablation as an intervention for **cervicogenic headache** ~~CHA~~, and 1/4 investigated **pulsed** ~~PRF~~ **RFA** ~~ablation~~ as an intervention for **cervicogenic headache** ~~CHA~~. None of the randomized studies showed strong evidence for **radiofrequency** ~~RF~~ and **pulsed RFA** ~~PRF ablation~~ as an effective intervention for **cervicogenic headache** ~~CHA~~. There were **two** ~~2~~ RCTs which did not show significant benefits with RFA. There is limited evidence for **radiofrequency** ~~RF~~ and pulsed RFA therapies for management of **cervicogenic headache** ~~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 **ON**~~occipital neuralgia~~. The authors found that a total of ~~3~~ **three** clinical studies and one case report investigating the use of ~~PRF~~ **pulsed radiofrequency** for **ON** ~~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 **pulsed radiofrequency** ~~PRF~~ as a treatment for **ON** ~~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 **ON** ~~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 ~~—~~**ON**~~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 **radiofrequency** (RF) intervention. When study populations and results were pooled, a total of 1253 **individuals** ~~patients~~ had undergone nerve decompression with an 86% success rate, 184 ~~patients~~ **individuals** were treated by nerve stimulation with a 68% success rate, and 131 ~~patients~~ **individuals** 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.

~~Huang et al. (2012) conducted~~ [WRM7] ~~a retrospective data analysis to evaluate the use of pulsed radiofrequency (PRF) for occipital neuralgia (ON ON) in 102 individualspatients. Fifty-two (51%) patientsindividuals 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 pulsed radiofrequency 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.~~

~~Vanelderen et al. (2010) reported~~ [WRM8] ~~on the results of a prospective trial with 6 months of follow-up in which pulsed radiofrequency pulsed radiofrequency treatment of the greater and/or lesser occipital nerve was used to treat ON occipital neuralgia in 19 individualspatients. ThosePatients presenting with clinical findings suggestive of ON 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 patientsindividuals 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 treatmentPRFT of the greater and/or lesser occipital nerve is a promising treatment of ONoccipital neuralgia. This study warrants further placebo-controlled trials.~~

~~Huang et al. (2012) conducted~~ [WRM9] ~~a retrospective data analysis to evaluate the use of pulsed radiofrequency (PRF) for occipital neuralgia (ON) in 102 patients. Fifty-two (51%) patients experienced~~ [WRM10] ~~≥ 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/Occipital Neuralgia

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**s** or **ON**~~occipital neuralgia~~. **N**~~There are n~~o well-designed **RCTs** ~~randomized controlled studies~~ in the medical literature **compare** ~~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.

In a 2023 prospective, double-blind, randomized, placebo-controlled, multicenter clinical trial, Tepper and colleagues enrolled 248 participants to assess the clinical efficacy of remote electrical neuromodulation (REN) for preventing migraine. Participants were randomized to a 1:1 ratio and observed for four weeks with an eight-week double-blind intervention in which participants utilized either REN or placebo stimulation (128 actives, 120 placebos). To assess results, participants recorded their symptoms daily

through an electronic diary. The modified intention-to-treat analysis consisted of 95 active and 84 placebo participants who qualified. The primary endpoint was measured from the mean number of migraine days per month from baseline, and the results showed a mean reduction of 4.0 ± SD of 4.0 days (1.3 ± 4.0 in placebo, therapeutic gain = 2.7 [CI−3.9 to −1.5], p< 0.001). The significance was maintained when analyzing the episodic (−3.2 ± 3.4 vs. −1.0 ± 3.6, p = 0.003) and chronic (−4.7 ± 4.4 vs. −1.6 ± 4.4, p = 0.001) migraine subgroups separately. REN was also superior to placebo in reduction of moderate/severe headache days (3.8 ± 3.9 vs. 2.2 ± 3.6, p = 0.005), reduction of headache days of all severities (4.5 ± 4.1 vs. 1.8 ± 4.6, p>< 0.001), percentage of patients achieving 50% reduction in moderate/severe headache days (51.6% [49/95] vs. 35.7% [30/84], p = 0.033), and reduction in days of acute medication intake (3.5 ± 4.1 vs. > < 0.001). The significance was maintained when analyzing the episodic (−3.2 ± 3.4 vs. −1.0 ± 3.6, p = 0.003) and chronic (−4.7 ± 4.4 vs. −1.6 ± 4.4, p = 0.001) migraine subgroups separately. REN was also superior to placebo in reduction of moderate/severe headache days (3.8 ± 3.9 vs. 2.2 ± 3.6, p = 0.005), reduction of headache days of all severities (4.5 ± 4.1 vs. 1.8 ± 4.6, p< 0.001), percentage of patients achieving 50% reduction in moderate/severe headache days (51.6% [49/95] vs. 35.7% [30/84], p = 0.033), and reduction in days of acute medication intake (3.5 ± 4.1 vs. 1.4 ± 4.3, p = 0.001). Comparable results were obtained in the ITT analysis. No serious device-related adverse events were reported in any group. The authors concluded that these results show that REN is a safe and effective preventive treatment for migraine, offering a much-needed non-pharmacological alternative as a stand-alone preventive therapy or combined with pharmacological therapies to enhance preventive impact further. The trial's limitations consist of a small sample size of participants who took additional preventative medications and those who did not; also, the definition of a migraine day included a possible combination of headache and aura, which does not comply with the IHS guidelines. Lastly, the inclusion criteria allowed for a single preventative agent, which limits the generalizability of the results in participants taking two or more preventatives (Included in the 2023 Hayes evolving evidence review).

In a 2022 randomized, sham-controlled, double-blind, multicenter trial, Tepper and colleagues evaluated the efficacy and safety of concurrent non-invasive stimulation of occipital and trigeminal nerves for the acute treatment of migraine with or without aura. The intention-to-treat group consisted of 131 participants, with 67 in the active group and 64 in the sham. One hundred nine participants were treated for at least one migraine episode, with 50 in the active group and 59 in the sham. The primary endpoint measured was the decrease of pain two hours subsequent treatment initiation. The secondary endpoints were pain relief at one hour and freedom from the most bothersome symptom at 2 hours post-treatment initiation. Exploratory endpoints consisted of freedom from the most painful symptom at two hours and sustained pain freedom 24 hours following treatment. Sixty percent of contributors (30/50) in the active arm described pain relief at two hours after the start of the first eligible treatment (primary outcome) versus 37% (22/59) in the control arm (difference, 23%; 95% CI‡, 2%-41%; p = 0.018). Pain freedom at two hours without rescue medicine was described by 46% (23/50) of contributors in the active arm and by 12% (7/59) of individuals in the sham arm (p < 0.001). Pain freedom two hours after the treatment and after 24 hours was described by 4.25 times more participants in the active arm (36%; 18/50) compared to the sham arm (8%; 5/59). The 28% difference was statistically significant (95% CI, 1%-43%; p < 0.001). A 4.25-fold difference was also seen associating the proportion of individuals free from pain and most bothersome symptom two h after the stimulation (47% [17/36] and 11% [5/45] in the active and sham arms, correspondingly; 95% CI, 14%-54%; p < 0.001).

A single-center, prospective, long-term open-label study was performed by Al-Kaisy et al. (2022) to evaluate the efficacy and safety of paresthesia-free high cervical 10 kHz spinal cord stimulation (SCS) in the treatment of ~~refractory chronic migraine (~~rCM~~)~~. Twenty adults with rCM (mean numbers of preventive treatments failed: 12.2 ±3.1) were enrolled and implanted with a 10 kHz SCS system (Senza™ system, Nevro Corp), with the distal tip of the lead(s) positioned epidurally at the C2 vertebral level. Safety and effectiveness outcomes including adverse events, headache and migraine reductions, responder rates **(RR)**, Migraine Disability Assessment (MIDAS), Headache Impact Test-6 (HIT-6), and Migraine-Specific Quality-of-Life (MSQ), were captured up to 52 weeks after implantation. Compared to baseline, at 52 weeks post-implantation, there was a reduction of mean monthly migraine days (MMD) by 9.3 days ($p < 0.001$). Sixty percent and 50% of **individuals** ~~patients~~ obtained respectively at least 30% and at least 50% reduction in mean MMD. By week 52, 50% of patients~~'~~' chronic pattern converted to an episodic pattern. The proportion of subjects classified with severe headache-related disability on the HIT-6, decreased from 100% to 60% at week 52. Meaningful improvements of headache-related quality of life measured by the MSQ scale were observed with mean gain of 24.9 ±23.1 ($p < 0.001$) points at 52 weeks. No unanticipated adverse device effects occurred. No patients required any additional device surgical revision. The authors concluded that 10 kHz SCS may a be safe and effective neurostimulation option for **individuals with** rCM ~~patients~~ stating that the paresthesia-free waveform constitutes an advantage for future methodologically sound sham-controlled studies in headache neuromodulation. A small sample size makes it difficult to decide whether these conclusions can be generalized to a larger population. Further research with **RCTs** ~~randomized controlled trials~~ is needed to validate these findings.

In 2021, Hayes conducted an Evolving Evidence Review on the Nerivio device (Theranica Bio-Electronics Ltd.) for the Treatment of Acute Migraine Episodes. At that time, the exploration of clinical studies and systematic reviews uncovered minimal support for using Nerivio for managing acute migraine episodes. After reviewing clinical practice guidelines and position statements, the review concluded there needed to be more guidance for using Nerivio to manage acute migraine episodes. The review suggests evidence comparing Nerivio with standard migraine care is needed to inform its real-world value as a treatment possibility. The review was updated in 2023, with the same conclusions for systematic reviews (minimal support) and weak support from clinical practice guidelines and position statements. Evaluation of the literature indicated that new evidence for the safety and efficacy has become available since the 2021 publication, which offers a possible upgrade in the current level of support from clinical studies to 'minimal support.' Overall, there was no new evidence with longer-term follow-up, or evidence comparing Nerivio with standard migraine care since the 2021 publication, leaving the conclusion of continued minimal support for the technology.

Joswig et al. (2021) performed a retrospective review of 96 patients with migraine, cervicogenic headache, cluster headache, neuropathic pain of the scalp, tension-type headache, and new daily persistent headache who had undergone ~~occipital nerve stimulation (~~ONS~~)~~ (61.5%), supraorbital nerve stimulation (SONS) (11.5%), or combined ONS plus SONS (27.1%) trial implantation and definitive implantation from 2007 to 2017. Changes in pain perception over time were monitored using the ~~visual analog scale (~~VAS~~)~~ for pain. The cohort consisted of 60.4% women and 39.6% men, with a mean age of 46.9 ±11.5 years and pain duration of 14 ±14.1 years. Of the 96 ~~patients~~ **participants**, 65 (67.7%) were treatment responders to a trial (≥ 30% amelioration in the average or maximum VAS score for pain and/or number of headache days) that had lasted 22.5 ±8.8 days. The reduction in their average VAS score for pain was to 37% ±24.4% of baseline compared with 99.1% ±24.1% of baseline for those without a response ($p < 0.01$). Of the 56 patients who had undergone

implantation and had long-term follow-up data available for ≤ 10 years, 32 (57.1%) reported a ≥ 50% reduction in their average VAS score for pain. Four **individuals** ~~patients~~ (6.5%) had requested hardware explanation. Stage II complications included ~~1~~ **one** infection (1.6%) and ~~6~~ **six** electrode dislocations (9.7%). The authors concluded that following careful patient selection, according to a positive response to a trial of ONS and/or SONS, clinically meaningful long-term benefit was achieved in 57.1% of **those** ~~the patients~~ with various chronic headache conditions. Study limitations included the retrospective nature, lack of controls receiving placebo intervention, and randomization.

Pohl et al. (2021) completed a ~~randomized controlled trial (~~RCT~~)~~ to test the hypothesis that self-administered anodal transcranial direct current stimulation (tDCS) over the visual cortex significantly decreases the number of **MMD** ~~monthly migraine days~~ in episodic migraine. The study was single-blind, randomized, and sham-controlled. Inclusion criteria were **individuals** ~~patients~~ aged 18-80 years and diagnosis of episodic migraine. Exclusion criteria were pregnancy, ~~presence of~~ a neurodegenerative disorder, a contraindication against MRI examinations, and less than two migraine days during the 28-day baseline period. ~~Patients in whom the~~ **Individuals whose** baseline period suggested chronic migraine were excluded. After baseline, participants applied daily either verum (anodal-1 mA to 20 min) or sham tDCS (anodal-1 mA to 30 sec) at Oz (reference Cz electrode) for 28 days. Headache diaries were used to record the number of migraine days at baseline, during the stimulation period, and during four subsequent 28-day periods. Twenty-eight patients were included; two were excluded after the baseline period because less than two migraine days occurred; three were excluded because their headache diaries suggested the diagnosis of chronic migraine. Twenty-three datasets were taken for further analysis. Compared to sham tDCS (n = 12), verum tDCS (n = 11) resulted in a lower number of migraine days (p = 0.010) across all follow-up periods. There was no change in total headache days (p = 0.165), anxiety (p = 0.884), or depression scores (p = 0.535). No serious adverse events occurred; minor side effects were similar in both groups. The authors concluded that this study provides Class II evidence that self-administered anodal tDCS over the visual cortex in ~~episodic migraine~~**EM** is safe, and results in a lower number of ~~-~~ **MMD**~~monthly migraine days~~. However, it has neither an immediate nor a long-term effect. Data suggest that tDCS has no effect on headaches other than migraine or on comorbid anxiety or depressive symptoms. Study limitations included the retrospective nature, lack of controls receiving placebo intervention, and the classification of individual attacks was based on the headache diary; non-migraine days were not classified. The findings of this study need to be validated by well-designed studies.

A systematic review of the efficacy and safety of **peripheral nerve stimulation (**~~-~~PNS**)** in managing acute or chronic pain was conducted by Xu et al. (2021). The review included ~~randomized controlled trials (~~RCTs~~)~~ and observational studies (n = 5) with Level I and II evidence of PNS in chronic migraine headache and Level II evidence in cluster headaches. The authors concluded that PNS of the occipital nerves reduced pain and disability and should be considered as an option for migraine and cluster headache when other noninvasive measures fail. There was a lack of high-quality RCTs. Meta-analysis was not possible due to wide variations in experimental design and heterogeneity of **the** study population.

Göbel et al. (2021) completed a prospective, randomized, interventional study to evaluate the effect of ~~occipital nerve stimulation (~~ONS~~)~~ on pain-modulatory mechanisms in the trigeminocervical area **for individuals** ~~in patients~~ with chronic migraine. In a balanced-repeated-measurements design in ~~8~~**eight individuals** ~~patients~~ with chronic migraine with and without active ONS, the authors analyzed which effects ONS had on the orbicularis oculi reflex dynamically elicited by corneal air flow. To stimulate the reflex response,

instead of an artificial electrical stimulus, a standardized air–flow is directed onto the cornea of the eye. The reflex response is recorded using a video camera detecting eyelid closure frequency (documented as eyelid closures per minute). This method aims to measure the anti-nociceptive protective mechanism of the orbicularis oculi reflex in a way as physiological as possible. At the same time, it allows recording the reflex response dynamically averaged over a longer period. The study was divided into two parts, the ON phase with active ONS, and the OFF phase with inactive ONS. In the former, the orbicularis oculi reflex was recorded quantitatively with active ONS. The OFF phase included the measurement of the orbicularis oculi reflex with ONS deactivated. There was a **one** ~~1~~-h break between the two test runs. To rule out a sequence effect, the **individuals** ~~patients~~ were randomized into two groups: One group (A) first went through the ON-phase measurement and, after an hour's break, the OFF-phase measurement. In the second group (B), the OFF-phase measurement was started, and the ON-phase measurement was carried out 1 h later. Results showed the orbicularis oculi reflex in active ONS (7.38 ±20.14 eyelid closures/minute) compared to inactive ONS (18.73 ±14.30 eyelid closures/minute) to be reduced (p = 0.021). The authors concluded that this suggests ONS can directly counteract the trigeminally mediated central sensitization in chronic migraine and protectively reduce the effects of aversive peripheral stimulation. A small sample size makes it difficult to decide whether these conclusions can be generalized to a larger population. Further research with **RCTs** ~~randomized controlled trials~~ **are** ~~is~~ needed to validate these findings.

A 2020 ECRI Clinical Evidence Assessment on Nerivio Migra reviewed clinical evidence from ~~2~~ **two** ~~sham-controlled~~ **sham controlled RCT** ~~randomized controlled trials~~, ~~2~~ **two** nonrandomized comparison studies, and **one** ~~1~~ large multicenter case series that addressed migraine pain, symptom relief, and adverse events ~~(AEs)~~. There was a total of 1,722 ~~patientsparticipants~~ **participants**. Two RCTs reported more **individuals** ~~patients~~ experienced pain relief with Nerivio (64% and 66.7%, respectively) than a sham treatment (26% and 38.8~~%)~~**%)**. One study reported that 89.7% of participants avoided medication during attacks. The authors concluded that additional RCTs are needed to characterize Nerivio's effectiveness as an alternative or adjunct to conventional treatments. Limitations ~~were identified which~~ included **ROB** ~~risk of bias~~ from small sample size and lack of a control group. **The updated 2022 ECRI Clinical Evidence Assessment states that consistent evidence shows Nerivio can decrease acute pain and medication use at 2 to 24-hour follow-up in 50% of individuals experiencing episodic, chronic, and/or menstrual migraine. The assessment notes that the technology is safe, with few mild adverse events reported. However, the studies reviewed are small, and confirmatory RCTs with long-term follow-up are necessary to determine safety and efficacy in the long term.**

A Hayes Health Technology Assessment report on **ONS** ~~occipital nerve stimulation~~ for chronic migraine headache identified **eight** ~~8~~ studies which included, **four** ~~4~~ ~~randomized controlled trials~~ **RCTs**, of which **two** ~~2~~ were crossover design; **one** ~~1~~ was an uncontrolled, open-label extension study of an RCT; and **four** ~~4~~ were prospective, uncontrolled studies. Sample size ranged from **eight** ~~8~~ to 157 ~~patients~~ **individuals** and follow-up ranged from **three** ~~3~~ months to **nine** ~~9~~ years. In all but **one** ~~1~~ study, ~~patients~~ **individuals** were selected for permanent ONS implantation based on a positive response to a temporary trial of ONS, typically, a ≥ 50% reduction in pain that lasted for a few weeks. The most reported outcome measures were the reduction in **headache** ~~HA~~ frequency and **headache** ~~HA~~ pain intensity. Other commonly reported outcome measures were response rate (most often defined as ≥ 50% reduction in **headache** ~~HA~~ frequency and/or intensity) and/or a ≥ 30% reduction~~,~~ ~~,~~ **headache** ~~HA~~-related disability, and **quality of life** ~~QOL~~. The report concluded that based on the available evidence, ONS appeared to have a positive but variable treatment effect on **headache** ~~HA~~ outcomes in selected patients, particularly in reductions

of frequency and intensity. There was a risk of complications that may require additional surgery. This conclusion was based on an overall low-quality body of evidence, inconsistent study designs and lack of a defined population**. One newly published study was uncovered in the 2022 Health Technology annual review. Hayes did not change their current rating, which reflects low-quality evidence of a potential benefit of ONS for improving headache outcomes in some individuals with chronic migraine. The update outlines how ONS is usually well tolerated; it may result in complications requiring additional surgeries (**Hayes, 2020a~~c~~**; updated 2022**). (Authors Dodick et al. **[**~~(~~2014**]**~~)~~** and Rodrigo et al. **[**~~(~~2017**]**~~)~~** which were previously cited in this policy, are included in this study).

A Hayes Health Technology Assessment report focused on ~~occipital nerve stimulation (~~ONS~~)~~ for the treatment of chronic cluster headache ~~(CH)~~ that had failed to respond to available drug treatments. The evidence base for this report included **one** ~~1~~ retrospective comparative cohort study, **four** ~~4~~ prospective or retrospective pretest/posttest studies, and **two** ~~2~~ prospective case series that evaluated ONS for treatment of **individuals with** chronic **cluster headache** ~~CH~~ (n = 15-67 individuals ~~patients~~ followed for **three** ~~3~~ months to 6.1 years). The reviewed studies did not provide sufficient evidence to evaluate the effectiveness of ONS for chronic **cluster headache** ~~CH~~. Across the studies that evaluated ONS for treatment of chronic **cluster headache** ~~CH~~, ~~patients~~ **individuals** achieved a clinically meaningful ≥ 50% decrease in **cluster headache** ~~CH~~ attacks from baseline in 41% to 90% of those treated. Reduction in intensity of pain during a **cluster headache** ~~CH~~ attack from baseline varied widely (range, 11%-96%) across studies, although ~~1~~ **one** study found a 2.3% increase in pain intensity that was not statistically significant. The study found that deep brain stimulation (DBS) was more effective than ONS with a greater number of **individuals** ~~patients~~ achieving a ≥ 50% decrease in **cluster headache** ~~CH~~ attacks from baseline in the DBS group than in the ONS group (100% versus 41%). Reduction in pain intensity scores was greater for the patients receiving DBS than patients receiving ONS (50% versus 11% reduction). Complications of ONS included uncomfortable or intolerable paresthesia (13%-35%), infection (2%-27%), pain or discomfort at wound or implant site (3%-24%), hardware or stimulation dysfunction (19%), wire or electrode breakage or migration (2%-17%), neck stiffness (16%), battery replacement needed < 1 year after implantation (12%), wire externalization or pressure ulcer due to wire or electrode (4%-9%), allergy to surgical material (4%), and wound issues (2%-4%). For infections and certain other complications, up to 27% of stimulators needed to be surgically removed or replaced. The body of evidence concerning ONS for chronic **cluster headache** ~~CH~~ was small in size and very low in quality. One of the reviewed studies was a comparative cohort study that was rated as poor quality. The other 6 studies were case series that were rated as poor or very poor. Larger, well-designed studies are needed to determine whether ONS is an effective treatment for refractory, chronic **cluster headache~~CH~~. In the updated 2022 Health Technology annual review, new evidence was uncovered; however, there was no new evidence with longer-term follow-up and no new technology applications. Hayes maintained their rating, which reflects very low-quality evidence that ONS provides some benefits for individuals with refractory symptoms due to chronic cluster headaches. Substantial uncertainty remains, with no concrete conclusions drawn due to the lack of controlled studies of ONS for cluster headaches and the small size of the controlled studies. The review shows that while ONS is generally safe, there is a risk of complications or need to remove the device over time.** (Hayes, 2020b**; updated 2022**). (Authors Magis et al. **[**~~(~~2011**]**~~)~~** and Miller et al. **[**~~(~~2017**]**~~)~~** which were previously cited in this policy, are included in this study).

~~A 2020 Hayes report addressed whether full-text clinical studies, systematic reviews, and clinical practice guidelines and position statements support the use of Nerivio Migra for~~

~~acute episodic migraines for pain relief. Three studies met inclusion criteria. The 3 records were 1 RCT and 2 secondary analyses of its data. A full-text review of clinical studies suggested minimal support for using Nerivio Migra for the management of acute migraine episodes. No systematic reviews were identified. A full-text review of clinical practice guidelines and position statement found no guidelines addressing remote electrical stimulation, or the Nerivio Migra device specifically were identified (Hayes, 2020a).~~

Moisset et al. (2020) performed a systematic review and meta-analysis of **RCTs** ~~randomized controlled trials~~ focusing on migraine treatment using neurostimulation methods. Outcomes for the quantitative synthesis were **two** ~~2~~-hour pain-~~-~~free for acute treatment and headache days per month for preventive treatment. Thirty-eight studies were included in the analysis (7 acute, 31 preventive). The authors concluded that **REN** ~~remote electrical neuromodulation~~ seemed effective for acute treatment. Invasive ~~occipital nerve stimulation~~ **ONS** was effective for chronic migraine prevention. Supra-orbital transcutaneous electrical nerve stimulation (TENS), percutaneous electrical nerve stimulation (PENS), and high-frequency repetitive transcranial magnetic stimulation (rTMS) over the motor cortex (M1) were effective for migraine prevention. The quality of the evidence was very poor. Future large and well-conducted studies are needed to confirm efficacy.

Aibar-Durán ~~Aibar-Duran~~ et al. (2020) describe two prospective cohorts of **individuals** ~~patients~~ with refractory cluster headache ~~(CH)~~ treated with ~~occipital nerve stimulation (~~ONS~~)~~ and ~~deep brain stimulation (~~DBS~~)~~ and compare preoperative to postoperative status at **six** ~~6~~ and 12 months after the surgery and at final follow-up. Efficacy analysis using objective and subjective variables is reported, as well as medication reduction and complications. The ONS group consisted of 13 men and **four** ~~4~~ women. The median number of attacks per week (N**a**~~A~~w) before surgery was 28, and the median follow-up duration was 48 months. The DBS group comprised **five** ~~5~~ men and **two** ~~2~~ women. The median Naw before surgery was 56, and the median follow-up was 36 months. The Naw and **VAS** ~~visual analog scale~~ score**s** were significantly reduced for the ONS and DBS groups after surgery. However, while all the patients from the DBS group were considered responders at final follow-up, with more than 85% being satisfied with the treatment, approximately 29% of initial responders to ONS became resistant by the final follow-up (p = 0.0253). The authors concluded that ONS is initially effective as a treatment for refractory **cluster headache** ~~CH~~, although a trend toward loss of efficacy was observed. No clear predictors of good clinical response were found in the present study. Conversely, DBS appears **effective and provides** ~~to be effective and provide~~ a more stable clinical response over time with an acceptable rate of surgical complications.

Halker et al. (2020) performed a systematic review to evaluate the effectiveness and comparative effectiveness of pharmacologic and nonpharmacologic therapies for the acute treatment of ~~episodic migraine~~**EM** in adults. Seventeen RCTs and one comparative observational study with 1,758 **participants** ~~patients~~ were included for nonpharmacologic therapies. The authors concluded that compared with placebo, several nonpharmacologic treatments may improve various measures of pain, including **REN** ~~remote electrical neuromodulation~~ (moderate **strength of evidence [**SOE**]**), magnetic stimulation (low SOE), acupuncture (low SOE), chamomile oil (low SOE), external trigeminal nerve stimulation (low SOE), and eye movement desensitization re-processing (low SOE). These interventions, including the noninvasive neuromodulation devices, have been evaluated only by single or very few trials.

A randomized, sham-controlled, parallel-~~-~~group, double-blind~~,~~ safety and efficacy study at 21 headache centers in the USA was conducted by Goadsby et al. (2019). Eligible participants were ~~aged~~ 22 years or older and had chronic cluster headaches (at least four attacks per week) that were either previously or currently inadequately controlled with available therapies. Participants were randomly assigned (1:1) to receive either sphenopalatine ganglion stimulation (n = 45) or sham stimulation (n = 48). Thirty-six **individuals** ~~patients~~ in the sphenopalatine ganglion stimulation group and 40 in the control group had at least one attack during the experimental phase and were included in efficacy analyses. The proportion of attacks for which pain relief was experienced at 15 minutes was 62·46% (95% CI 49·15-74·12) in the sphenopalatine ganglion stimulation group versus 38·87% (28·60-50·25) in the control group (odds ratio 2·62 [95% CI 1·28-5·34]; p = 0·008). Nine serious adverse events were reported. Three of these serious adverse events were related to the implantation procedure (aspiration during intubation, nausea and vomiting, and venous injury or compromise). A fourth serious adverse event was an infection that was attributed to both the stimulation device and the implantation procedure. The other five serious adverse events were unrelated. The authors concluded that sphenopalatine ganglion stimulation seems efficacious and is well tolerated, and potentially offers an alternative approach to the treatment of chronic cluster headache. Further research is needed to clarify its place in clinical practice.

A monocenter, prospective, open-label, pilot trial (Birlea et al., 2019) explored the therapeutic utility and safety of external trigeminal neurostimulation (eTNS) as a preventive treatment in patients suffering from chronic migraine ~~(CM)~~. Participants were adult patients with a history of **chronic migraine** ~~CM~~ meeting International Classification of Headache Disorder-3 beta (2013) diagnostic criteria with or without medication overuse. After a **one** ~~1~~-month baseline period, 58 patients applied at least one daily 20-min session of eTNS for **three** ~~3~~ months. Primary outcomes were mean monthly changes in frequency of headache days and in overall acute headache medication intake. Compared to baseline, frequency of headache days decreased by 3.12 days (16.21%, p < 0.001) and acute medication intake decreased from 26.33 to 18.22 (30.81%, p < 0.001) during the third month of treatment. Twenty-six patients reported 47 minor adverse events, of which only **two** ~~2~~ were related to the use of the device (skin irritation under the electrode and headache worsening with vertigo). The authors concluded that this open-label pilot trial suggests that eTNS with the Cefaly® device is safe and effective as prophylactic treatment for **chronic migraine** ~~CM~~ in adult patients. The treatment effect is greatest in patients with noncontinuous headache; it is hardly significant in those with continuous ~~headache. The~~**headache. The study's open-label design and the lack of placebo arm are a limitation.** ~~A limitation of the study is its open-label design and the lack of placebo arm.~~ The fact that the number of daily eTNS sessions was not the same for all **individuals** ~~patients~~ could be considered another weakness of the trial protocol, producing unnecessary variability.

A 2019 ECRI Health Technology Assessment on ~~occipital nerve stimulation~~ **ONS** for treating medically refractory chronic cluster headache found that evidence from ~~6~~ **six** small case series at high ~~-~~ **ROB** ~~risk of bias~~ is insufficient to determine how well ONS works or how it compares with other electrical stimulation options ~~in patients~~ **for individuals** with chronic **cluster headache** ~~CH~~ that has not responded well to medical therapy. Side effects from ONS are common and include lead migration and local inflammation. Although studies reported reductions in headache frequency in more than half of patients, results need validation from ~~randomized controlled trials (~~RCTs~~).~~ ~~(ECRI, 2019).~~

Tao et al. (2018) conducted a meta-analysis to analyze ~~the effectiveness and safety of transcutaneous electrical nerve stimulation (~~TENS~~)~~ **effectiveness and safety for**

~~invidualsindividuals with migraines.~~ ~~on patients with migraine~~. The study included four **RCTs**~~randomized controlled trials~~, which compared the effect of TENS (n = 161) with sham TENS (n = 115). Change in the number of monthly headache days **(MHD)**, ~~responder rate~~ **RR**, painkiller intake, adverse events and satisfaction were extracted as outcome. The authors concluded that there is low~~-~~-quality evidence suggesting that TENS may be effective in increasing ~~responder rate~~ **RR**, reducing headache days and painkiller intake, serving as a well-tolerated alternative for migraineurs. Future well-designed RCTs with extensive follow-up are needed.

~~An uncontrolled~~ [WRM11]~~open-label prospective study was conducted by Miller et al. (2018). Thirty-one participants patients with intractable short-lasting unilateral neuralgiform headache attacks were treated with bilateral occipital nerve stimulation. At a mean follow-up of 44.9 months (range 13-89), there was a 69% improvement in attack frequency with a response rate (defined as at least a 50% improvement in daily attack frequency) of 77%. Attack severity reduced by 4.7 points on the verbal rating scale and attack duration by a mean of 64%. Improvements were seen in headache-related disability and depression. Adverse event rates were favorable, with no electrode migration or erosion reported. The authors concluded that occipital nerve stimulationONS appears to offer a safe and efficacious treatment for refractory short-lasting unilateral neuralgiform headache attacks. This is an uncontrolled study with a small sample size.~~

~~Chen et al. (2015)~~ [WRM12]~~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.~~

A randomized blind control study aimed to assess the effectiveness and safety of ~~percutaneous electrical nerve stimulation (~~PENS~~)~~ in migraine treatment was conducted by Li and Xu (2017). Sixty-two **individuals** ~~patients~~ with at least ~~2~~ **two** migration attacks each month were recruited and randomly divided into a PENS group and a sham PENS group in a ratio of 1:1. All **participants** ~~patients~~ received PENS or sham PENS 30 minutes daily, **five** ~~5~~ times weekly for 12 weeks. All outcome measurements were performed at treatment initiation to establish a baseline and after 12 weeks of treatment. The authors report that at the end of the 12 weeks, the group receiving PENS exhibited statistically significant decrease in the mean in ~~monthly migraine days (~~MMD~~)~~ compared with the group receiving sham PENS intervention. The 50% ~~responder rate (~~RR~~)~~ was significantly higher in the PENS group than that in the sham PENS group. The monthly migraine attacks (MMA),

~~monthly headache days (~~MHD~~)~~, and monthly acute antimigraine drug intake (MAADI) were also significantly lower in the PENS group that those in the sham PENS group. The authors concluded that the results of the study demonstrated that PENS is more effective and safer than Sham PENS for the treatment of migraine. Follow-up regarding both short and long-term effectiveness of PENS for treatment of migraine still needs to be assessed.

Liu et al. (2017) performed a randomized, controlled trial of transcutaneous occipital nerve stimulation (tONS) for prevention of migraine to evaluate the efficacy and tolerability of tONS **for** ~~in patients with~~ **individuals with** migraine. **Participants** ~~Patients~~ (n = 110) were randomized to **one** ~~1~~ of **five** ~~5~~ therapeutic groups before treatment for **one** ~~1~~ month. Groups A through C received tONS at different frequencies, group D underwent sham tONS intervention, and group E received topiramate orally. The authors report that the 50% ~~responder rate~~ **RR** was significantly greater in the groups undergoing active tONS and topiramate, compared with sham-treated group. A significant reduction in headache intensity was noted in each test group compared with the sham group. They concluded that tONS therapy is a new promising approach for migraine prevention. It has infrequent and mild adverse events and may be effective among **those** ~~patients~~ who prefer nonpharmacological treatment. The findings of this study need to be validated by well-designed studies with long-term follow-up.

Mekhail et al. (2016) presented 52-week safety and efficacy results from an open-label extension of a randomized, sham-controlled trial for **individuals** ~~patients~~ with chronic migraine ~~(CM)~~ undergoing ~~peripheral nerve stimulation~~ **PNS** of the occipital nerves. In this single~~-~~-center, 20 **participants** ~~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. Outcomes collected included number of headache days, pain intensity, Migraine Disability Assessment (MIDAS), Zung Pain and Distress (PAD), direct ~~patient~~ reports of headache pain relief, quality of life, satisfaction, and adverse events. ~~(Aes).~~ Headache days per month were reduced by 8.51 (± 9.81) days. The proportion of **individuals** ~~patients~~ who achieved a 30% and 50% reduction in headache days and/or pain intensity was 60% and 35%, respectively. MIDAS and Zung PAD were reduced for all patients. Fifteen (75%) of the 20 patients at the site reported at least one~~-~~ **adverse event**~~AE~~. A total of 20 **adverse events** ~~AEes were~~**was** reported from the site. The authors concluded that their results supported the 12-month efficacy of 20 **individuals with chronic migraine** ~~CM patients~~ receiving ~~peripheral nerve stimulation~~**PNS** of the occipital nerves. The significance of this study is limited by small sample size and short follow-up period.

Chen et al. (2015) conducted a systematic review to examine the effectiveness and adverse effects of ONS for chronic migraine. Five 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 participants received either active or sham stimulation. ONB and intraoperative testing were performed in the fourth center. The blinded phase was followed by an open-~~-~~label phase of one-three~~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). Participants in the trials had between 19-22 days with prolonged, moderate or severe headache per month at baseline. Those 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 individuals 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.

~~Vadivelu et al. (2011) evaluated 18 patients~~ individuals [WRM13]~~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~~ individuals ~~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~~ individuals with CMI ~~CMI patients and~~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.~~

~~In a set of recommendations~~ [WRM14]~~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).~~

~~Slavin et al. (2006)~~ [WRM15]~~analyzed the records of 14 consecutive patients~~ [WRM16]~~with intractable ON 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.~~

Clinical Practice Guidelines

American Academy of Pain Medicine (AAPM) Foundation

The AAPM developed a multidisciplinary panel of eight physicians, two psychologists, and one patient representative to review the multidisciplinary preventative options for migraine management in three categories: medications, behavioral, and interventional strategies. The panel concluded there is low certainty of evidence that GONBs with local anesthetic are more effective than saline injections in reducing headache days or acute medication use per month. There is insufficient evidence that GONBs with local anesthetic are more effective than saline in reducing patient impairment, as defined by PROs. The adverse event profile is minimal. Overall, the committee gave GONBs a weak recommendation for the prevention of chronic migraine and found insufficient evidence of efficacy for episodic migraine. This treatment may be more effective for acute or short-term

preventive therapy, and further research should be directed to those areas (Barad et al., 2022).

American Society of Anesthesiologists (ASA)

In their practice statement on post-dural puncture headache management (PDPH), the ASA stated that there is insufficient evidence to recommend the use of **GONBs** ~~greater occipital nerve blocks~~ or sphenopalatine ganglion blocks in the treatment of obstetric PDPH (ASA, 2021).

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: "Subcutaneous ~~peripheral nerve stimulation~~ **PNS** may be used in the multimodal treatment of patients with painful peripheral nerve injuries who have not responded to other therapies" (ASA/ASRA, 2010).

American Headache Society (AHS)

A 2019 AHS position statement on integrating new migraine treatments into clinical practice states that neuromodulation and biobehavioral therapy may be appropriate for preventive and acute treatment, depending on the needs of individual patients. Neuromodulation may be helpful for individuals who prefer nondrug therapies, respond poorly, cannot tolerate, or have contraindications to pharmacotherapy (AHS, 2019).

A 2016 AHS guideline for treating cluster headaches recommends (Level A) sumatriptan subcutaneously, zolmitriptan nasal spray, and high-flow oxygen for acute treatment. Sphenopalatine ganglion stimulation has been administered as a Level B recommendation for acute treatment. Suboccipital steroid injections have emerged as the only treatment to receive a Level A recommendation. Other newly evaluated treatments have been given a Level B recommendation (negative study: DBS), a Level C recommendation (positive study: warfarin; negative studies: cimetidine/chlorpheniramine, candesartan), or a Level U (data inadequate or conflicting) recommendation (frovatriptan). Further studies are warranted to demonstrate the safety and efficacy of established and emerging therapies (Robbins et al., 2016).

To draw attention to tests and procedures associated with low-value care in headache medicine, the 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 not to recommend surgical deactivation of migraine trigger points outside of a clinical trial (Loder et al., 2013).

AHS has issued a statement about the 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~~ AHS, there are no convincing or definitive data, to date, ~~that~~ which 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)..

American Society of Interventional Pain Physicians (ASIPP)

A 2013 ASIPP guideline recommends that "therapeutic neurotomy may be provided based on the response from controlled diagnostic blocks."

Congress of Neurological Surgeons

The Congress of Neurological Surgeons published an evidence-based guideline in 2015 supporting the use of **ONS** ~~occipital nerve stimulation~~ as a treatment option for **individuals** ~~patients~~ with medical refractory **ON**~~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).

Department of Veterans Affairs and the Department of Defense (VA/DoD)

A 2020 VA/DoD Clinical Practice Guideline for the primary care management of headache found there is insufficient evidence to recommend for or against the following for headache:

- Transcranial magnetic stimulation
- Transcranial direct current stimulation
- Pulsed radiofrequency or sphenopalatine ganglion block
- External trigeminal nerve stimulation
- Supraorbital electrical stimulation
- Neuromodulation

European Headache Federation

In a set of recommendations regarding neuromodulation for chronic headaches, the European Headache Federation states that despite a growing field of stimulation devices in headaches treatment, further controlled studies are warranted to validate, strengthen and disseminate the use of neurostimulation. The European Headache Federation states that until these data are available, any neurostimulation device should only be used for individuals 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).

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).

National Comprehensive Cancer Network (NCCN)

The ~~National Comprehensive Cancer Network (~~NCCN~~)~~ practice guidelines (2022) for adult cancer pain indicate that interventional therapies that can be useful in the relief of

cancer pain include nerve blocks, vertebral augmentation, regional infusion of analgesics, neurostimulation and RF ablation. This recommendation is based on category 2A level of evidence (based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate).

National Institute for Health and Care Excellence (NICE)

A 2015 NICE guideline for the implantation of a sphenopalatine ganglion stimulation device for chronic cluster headache has the following states that current evidence on the efficacy of implantation of a sphenopalatine ganglion stimulation device for chronic cluster headache, in the short term (up to 2 months), is adequate. A variety of complications have been documented, most of which occur early and resolve; surgical revision of the implanted system is sometimes needed. The procedure should only be used with special arrangements for clinical governance, consent and audit or research. NICE encourages further research on sphenopalatine ganglion stimulation for chronic cluster headache. ~~(NICE, 2015).~~

~~The National Institute for Health and Care Excellence (~~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 **individuals** ~~patients~~ with the best possible advice (NICE 2013).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

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. (Accessed ~~April 22, 2022~~ **March 3, 2023**)

Electrical Stimulation

Electrical stimulation of the occipital/cranial nerves for the treatment of occipital neuralgia, cervicogenic headache and migraines 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. There are numerous devices listed in the FDA 510(k) database with product codes GZF, GZB and PCC. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed ~~April 22, 2022~~ **March 3, 2023**)

References

Acar F, Miller J, Golshani KJ, et al. Pain relief after cervical ganglionectomy (C2 and C3) for the treatment of medically intractable occipital neuralgia. Stereotact Funct Neurosurg. 2008;86(2):106-12.

Aibar-Durán JÁ, Álvarez Holzapfel MJ, Rodríguez R, et al. Occipital nerve stimulation and deep brain stimulation for refractory cluster headache: a prospective analysis of efficacy over time. J Neurosurg. 2020 Jan 17:1-8.

Al-Kaisy A, Palmisani S, Carganillo R, et al. Safety and efficacy of 10 kHz spinal cord stimulation for the treatment of refractory chronic migraine: a prospective long-term open-label study. Neuromodulation. 2022 Jan;25(1):103-113.

~~Allen SM, Mookadam F, Cha SS, et al. Greater occipital nerve block for acute treatment of migraine headache: a large retrospective cohort study. J Am Board Fam Med. 2018 Mar-Apr;31(2):211-218.~~

Ambrosini A and Schoenen J. Invasive pericranial nerve interventions. Cephalalgia 2016, Vol. 36(12) 1156–1169.

American Headache Society (AHS). Surgical intervention in migraine treatment. Position Statement. April 2012.

American Headache Society. The American Headache Society Position Statement ~~On~~on Integrating New Migraine Treatments Into Clinical Practice. Headache. 2019 Jan;59(1):1-18.

American Migraine Foundation. Understanding migraine cervicogenic headache. October 24, 2016.

American Society of Anesthesiologists Obstetric Anesthesia Committee. Statement on post-dural puncture headache management. October 13, 2021. https://www.asahq.org/standards-and-guidelines/statement-on-post-dural-puncture-headache-management. ~~Accessed March~~ **Accessed March 10, 2023** ~~April 22, 2022~~.

American Society of Anesthesiologists Task Force on Chronic Pain Management; American Society of Regional Anesthesia and Pain Medicine (ASA/ASRA). Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management, and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology.2010;112(4):810-833.

American Society of Interventional Pain Physicians Interventional Pain Management. 2013. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. part ii: guidance and recommendations.

~~Ashkenazi A, Blumenfeld A, Napchan U, et al. Peripheral nerve blocks and trigger point injections in headache management -- a systematic review and suggestions for future research. Headache. 2010 Jun;50(6):943-52.~~

Baldelli I, Mangialardi ML, Salgarello M, **et al.** ~~Raposio E.~~ Peripheral occipital nerve decompression surgery in migraine headache. Plast Reconstr Surg Glob Open. 2020 Oct 14;8(10):e3019.

Barad M, Ailani J, Hakim SM, et al. Percutaneous interventional strategies for migraine prevention: a systematic review and practice guideline. Pain Med. 2022 Jan 3;23(1):164-188.

Birlea M, Penning S, Callahan K, Schoenen J. Efficacy and safety of external trigeminal neurostimulation in the prevention of chronic migraine: an open-label trial. Cephalgia. 2019;2:1-10.

Blake P, Nir RR, Perry CJ, **et al.** ~~Burstein R.~~ Tracking patients with chronic occipital headache after occipital nerve decompression surgery: a case series. Cephalalgia. 2019 Apr;39(4):556-563.

Caponnetto V, Ornello R, Frattale I, et al. Efficacy and safety of greater occipital nerve block for the treatment of cervicogenic headache: a systematic review. Expert Rev Neurother. 2021 May;21(5):591-597.

Chang YJ, Hung KC, Chen IW, et al. Efficacy of greater occipital nerve block for pain relief in patients with postdural puncture headache: A meta-analysis. Medicine (Baltimore). 2021 Dec 23;100(51):e28438.

Chen G, You H, Juha H, et al. Trigger areas nerve decompression for refractory chronic migraine. Clin Neurol Neurosurg. 2021 Jul;206:106699.

Chen Y-F, Bramley G, Unwin, ~~Gemma,~~ et al. Occipital nerve stimulation for chronic migraine—a systematic review and meta-analysis. PloS ONE10(3): March 20, 2015.

Choi KS, Ko Y, Kim YS, et al. Long-term outcome and prognostic factors after C2 ganglion decompression in 68 consecutive patients with intractable occipital neuralgia. Acta Neurochir (Wien). 2015 Jan;157(1):85-92. I.

Chowdhury D, Tomar A, Deorari V, et al. Greater occipital nerve blockade for the preventive treatment of chronic migraine: a randomized double-blind placebo-controlled study. Cephalalgia. 2023 Feb;43(2):3331024221143541.

Cuadrado ML, Aledo-Serrano Á, Navarro P, et al. Short-term effects of greater occipital nerve blocks in chronic migraine: a double-blind, randomized, placebo-controlled clinical trial. Cephalalgia. 2017;37(9):864-872.

Deer TR, Mekhail N, Petersen E, et al. The appropriate use of neurostimulation: stimulation of the intracranial and extracranial space and head for chronic pain. Neuromodulation. 2014 Aug;17(6):551-70; discussion 570.

Diener HC, Kaminski M, Stappert G, et al. Lower cervical disc prolapse may cause cervicogenic headache: prospective study in patients undergoing surgery. Cephalalgia. 2007 Sep;27(9):1050-4.

Department of Veterans Affairs and the Department of Defense Clinical Practice Guideline for the primary care management of headache. Version 1.0. July 2020.

Dilli E, Halker R, Vargas B, et al. Occipital nerve block for the short-term preventive treatment of migraine: a randomized, double-blinded, placebo-controlled study. Cephalalgia. 2014 Dec 12.

Dodick DW, Silberstein SD, Reed KL, et al. Safety and efficacy of peripheral nerve stimulation of the occipital nerves for the management of chronic migraine: long-term results from a randomized, multicenter, double-blinded, controlled study. Cephalalgia. 2014 Jul 30.

Ducic I, Felder JM 3rd, Fantus SA. A systematic review of peripheral nerve interventional treatments for chronic headaches. Ann Plast Surg. 2014 Apr;72(4):439-45.

Ducic I, Hartmann EC, Larson EE. Indications and outcomes for surgical treatment of patients with chronic migraine headaches caused by occipital neuralgia. Plast Reconstr Surg. 2009 May;123(5):1453-61.

ECRI. Nerivio Migra (Theranica Bioelectronics, Ltd.) Remote electrical neuromodulator for treating migraine headache. Plymouth Meeting (PA): ECRI; 2020 **Oct; updated 2022 May** ~~Oct 15~~. (Clinical Evidence Assessment).

ECRI Institute. Occipital nerve stimulation for treating medically refractory chronic cluster headache. Plymouth Meeting (PA): ECRI Institute; 2019 July 31. (Custom Rapid Responses).

ECRI Institute. Radiofrequency Denervation for Treating Cervical Facet Joint Pain. Plymouth Meeting (PA): ECRI Institute; 2018 May 01. (Custom Rapid Responses). Archived report.

Fang L, Jingjing L, Ying S, et al. Computerized tomography-guided sphenopalatine ganglion pulsed radiofrequency treatment in 16 patients with refractory cluster headaches: Twelve- to 30-month follow-up evaluations. Cephalalgia 2016, Vol. 36(2) 106–112.

Friedman BW, Irizarry E, Williams A, et al. A randomized, double-dummy, emergency department-based study of greater occipital nerve block with bupivacaine vs intravenous metoclopramide for treatment of migraine. Headache. 2020 Nov;60(10):2380-2388.

Gande AV, Chivukula S, Moossy JJ, et al. Long-term outcomes of intradural cervical dorsal root rhizotomy for refractory occipital neuralgia. J Neurosurg. 2016 Jul;125(1):102-10.

Goadsby PJ, Sahai-Srivastava S, Kezirian EJ, et al. Safety and efficacy of sphenopalatine ganglion stimulation for chronic cluster headache: a double-blind, randomized controlled trial. Lancet Neurol. 2019 Dec;18(12):1081-1090.

Göbel CH, Heinze A, Karstedt S, et al. Effect of occipital nerve stimulation (ONS) on the orbicularis oculi reflex triggered by a standardized air flow in patients with chronic migraine-a prospective, randomized, interventional study. Pain Ther. 2021 Jun;10(1):567-576.

Gönen M, Balgetir F, Aytaç E, et al. Suboccipital steroid injection alone as a preventive treatment for cluster headache. J Clin Neurosci. 2019 Oct;68:140-145.

Goyal S, Kumar A, Mishra P, et al. Efficacy of interventional treatment strategies for managing patients with cervicogenic headache: a systematic review. Korean J Anesthesiol. 2022 Feb;75(1):12-24.

Govindappagari S, Grossman TB, Dayal AK, et al. Peripheral nerve blocks in the treatment of migraine in pregnancy. Obstet Gynecol. 2014 Dec;124(6):1169-74.

Grandhi RK, Kaye AD, Abd-Elsayed A. Systematic review of radiofrequency ablation and pulsed radiofrequency for management of cervicogenic headaches. Curr Pain Headache Rep. 2018;22(3):18.

Guerrero ÁL, Herrero-Velázquez S, Peñas ML, et al. Peripheral nerve blocks: a therapeutic alternative for hemicrania continua. Cephalalgia. 2012 Apr;32(6):505-8.

Gul HL, Ozon AO, Karadas O, et al. The efficacy of greater occipital nerve blockade in chronic migraine: a placebo-controlled study. Acta Neurol Scand. 2017;136(2):138-144.

Guo Y, Wang X, Bian J, et al. Low-temperature plasma radiofrequency ablation for the management of refractory cluster headache. Wideochir Inne Tech Maloinwazyjne. 2021 Jun;16(2):362-368.

Guyuron B, Kriegler JS, Davis J, et al. Five-year outcome of surgical treatment of migraine headaches. Plast Reconstr Surg. 2011;127(2):603-608.

Guyuron B, Reed D, Kriegler JS, et al. A placebo-controlled surgical trial of the treatment of migraine headaches. Plast Reconstr Surg. 2009 Aug;124(2):461-8.

Halker Singh RB, VanderPluym JH, Morrow AS, et al. Acute treatments for episodic migraine. Comparative Effectiveness Review No. 239. AHRQ Publication No. 21-EHC009. Rockville, MD: Agency for Healthcare Research and Quality; December 2020.

Hasırcı Bayır BR, Gürsoy G, Sayman C, et al. Greater occipital nerve block is an effective treatment method for primary headaches? Agri. 2022 Jan;34(1):47-53.

Hayes, Inc. Evidence Analysis Research Brief. Local injection therapy for cervicogenic headache and occipital neuralgia. Hayes, Inc.; February 2, 2023.

~~Hayes, Inc. Evidence Analysis Research Brief. Remote electrical neuromodulation using Nerivio Migra (Theranica Bio-Electronics Ltd) for treatment of migraines. Lansdale, PA: Hayes, Inc.; October 14, 2019a. Archived July 1, 2020.~~

~~Hayes, Inc. Evolving Evidence Review. Nerivio Migra for treatment of acute migraine. Lansdale, PA: Hayes, Inc.; July 1, 2020a.~~

Hayes, Inc. Evolving evidence Review. Nerivio (Theranica Bio-Electronics Ltd.) for Treatment of Acute Migraine Episodes. Hayes, Inc.; July 23, 2021.

Hayes, Inc. Health Technology ~~Assessment .~~**Assessment.** Local injection therapy for cervicogenic headache and occipital neuralgia. ~~Lansdale, PA:~~ Hayes, Inc.; September 28, 2017.~~**Archived October 28, 2022.** Updated November 15, 2021~~.

Hayes, Inc. Hea**l**t~~l~~h Technology Assessment. Occipital nerve stimulation for chronic cluster headache. ~~Lansdale, PA:~~ Hayes, Inc.; September 24, 2020b. **Updated October 24, 2022.**

Hayes, Inc. Health Technology Assessment. Occipital nerve stimulation for chronic migraine headache. ~~Lansdale, PA:~~ Hayes, Inc.; June 30, 2020**a**~~c~~. **Updated June 13, 2022.**

Hayes, Inc. Health Technology Brief. Greater Occipital Nerve Blocks for Treatment of Migraine. ~~Lansdale, PA:~~ Hayes, Inc.; September 5, 2019~~b~~. Updated ~~.~~**October 10, 2022.** ~~October 6, 2021.~~

~~Huang JH, Galvagno SM Jr, Hameed M, et al. Occipital nerve pulsed radiofrequency treatment: a multi-center study evaluating predictors of outcome. Pain Med. 2012 Apr;13(4):489-97.~~

Inan LE, Inan N, Coskun, ~~Ozlem,~~ et al. Greater occipital nerve blockade for the treatment of chronic migraine: a randomized, multicenter, double-blind, and placebo-controlled study. Acta Neurol Scand. March 13, 2015.

Jansen J, Sjaastad O. Cervicogenic headache. Smith/Robinson approach in bilateral cases. Funct Neurol. 2006 Oct-Dec;21(4):205-10.

Jansen J, Sjaastad O. Cervicogenic headache: long-term prognosis after neck surgery. Acta Neurol Scand. 2007 Mar;115(3):185-91.

Jansen J. Surgical treatment of cervicogenic headache. Cephalalgia. 2008 Jul;28 Suppl 1:41-4.

Jose A, Nagori SA, Chattopadhyay PK, et al. Greater occipital nerve decompression for occipital neuralgia. J Craniofac Surg. 2018 Jul;29(5):e518-e521.

Joswig H, Abdallat M, Karapetyan V, et al. Long-term experience with occipital and supraorbital nerve stimulation for the various headache disorders-a retrospective institutional case series of 96 patients. World Neurosurg. 2021 Jul;151:e472-e483.

Kashipazha D, Nakhostin-Mortazavi A, Mohammadianinejad SE, et al. Preventive effect of greater occipital nerve block on severity and frequency of migraine headache. Glob J Health Sci. 2014 Jul 29;6(6):209-13.

Keifer OP Jr, Diaz A, Campbell M, et al. Occipital nerve stimulation for the treatment of refractory occipital neuralgia: a case series. World Neurosurg. 2017 Sep;105:599-604.

Korucu O, Dagar S, Corbacioglu SK, et al. The effectiveness of greater occipital nerve blockade in treating acute migraine-related headaches in emergency departments. Acta Neurol Scand. 2018 Sep;138(3):212-218.

Lambru G, Abu Bakar N, Stahlhut L, et al. Greater occipital nerve blocks in chronic cluster headache: a prospective open-label study. Eur J Neurol. 2014 Feb;21(2):338-43.

Lauretti GR, Corrêa SW, Mattos AL. Efficacy of the greater occipital nerve block for cervicogenic headache: comparing classical and sub compartmental techniques. Pain Pract. 2014 Jul 4.

Lee HJ, Cho HH, Nahm FS, et al. Pulsed radiofrequency ablation of the C2 dorsal root ganglion using a posterior approach for treating cervicogenic headache: a retrospective chart review. Headache. 2020.

Li F, Ma Y, Zou J, et al. Micro-surgical decompression for greater occipital neuralgia. Turk Neurosurg. 2012;22(4):427-9.

Li H, Xu QR. Effect of percutaneous electrical nerve stimulation for the treatment of migraine. Medicine (Baltimore). 2017 Sep;96(39):e8108.

Liu Y, Dong Z, Wang R, et al. Migraine prevention using different frequencies of transcutaneous occipital nerve stimulation: a randomized controlled trial. J Pain. 2017 Apr 17

Loder E, Weizenbaum E, Frishberg B, et al. American Headache Society Choosing Wisely Task Force. Choosing Wisely in Headache Medicine: The American Headache Society's List of Five Things Physicians and Patients Should Question. Headache. 2013 Nov;53(10):1651-9.

Luo F, Lu J, Ji N. Treatment of refractory idiopathic supraorbital neuralgia using percutaneous pulsed radiofrequency. Pain Pract. 2018 Feb 26.

Magis D, Gerardy PY, Remacle JM, **et al.** ~~Schoenen J.~~ Sustained effectiveness of occipital nerve stimulation in drug-resistant chronic cluster headache. Headache. 2011 Sep;51(8):1191-201.

Malekian N, Bastani PB, Oveisgharan S, et al. Preventive effect of greater occipital nerve block on patients with episodic migraine: a randomized double-blind placebo-controlled clinical trial. Cephalalgia. 2022 May;42(6):481-489.

Manolitsis N, Elahi F. Pulsed radiofrequency for occipital neuralgia. Pain Physician. 2014 Dec;17(6):E709-17.

Martelletti P, Jensen RH, Antal A, et al. Neuromodulation of chronic headaches: position statement from the European Headache Federation. J Headache Pain. 2013 Oct 21;14:86.

McNutt S, Hallan DR, Rizk E. Evaluating the Evidence: Is neurolysis or neurectomy a better treatment for occipital neuralgia? cureus. 2020 Nov 12;12(11):e11461.

Mekhail NA, Estemalik E, Azer G, et al. Safety and efficacy of occipital nerves stimulation for the treatment of chronic migraines: Randomized, double-blind, controlled single-center experience. Pain Pract. 2016 Oct 25.

~~Miller S, Watkins L, Matharu M. Long-term follow up of intractable chronic short lasting unilateral neuralgiform headache disorders treated with occipital nerve stimulation. Cephalalgia. 2018 Apr;38(5):933-942.~~

Miller S, Watkins L, Matharu M. Treatment of intractable chronic cluster headache by occipital nerve stimulation: a cohort of 51 patients. Eur J Neurol. 2017 Feb;24(2):381-390.

Moisset X, Pereira B, Ciampi de Andrade D, et al. Neuromodulation techniques for acute and preventive migraine treatment: a systematic review and meta-analysis of randomized controlled trials. J Headache Pain. 2020 Dec 10;21(1):142.

Nagar Vittal R, Birthi Pravardhan, Grider Jay, et al. Systematic review of radiofrequency ablation and pulsed radiofrequency for management of cervicogenic headache. Pain Physician 2015; 18:109-130.

National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Adult Cancer Pain. January 19, 2023~~2~~; v.1.2023~~2~~.

National Institute for Health and Care Excellence (NICE). Interventional procedures guidance 527. Implantation of a sphenopalatine ganglion stimulation device for chronic cluster headache. June 2015.

National Institute for Health and Care Excellence (NICE). Interventional procedures guidance 452. Occipital Nerve Stimulation for Intractable Chronic Migraine. April 2013.

Niraj G, Kelkar A, Girotra V. Greater occipital nerve block for postdural puncture headache (PDPH): a prospective audit of a modified guideline for the management of PDPH and review of the literature. J Clin Anesth. 2014 Nov;26(7):539-44.

~~Okmen K, Dagistan Y, Dagistan E, et al. Efficacy of the greater occipital nerve block in recurrent migraine type headaches. Neurol Neurochir Pol. 2016;50(3):151-4.~~

Orhurhu V, Huang L, Quispe RC, et al. Use of radiofrequency ablation for the management of headache: a systematic review. Pain Physician. 2021 Nov;24(7):E973-E987.

Özer D, Bölük C, Türk Börü Ü, et al. Greater occipital and supraorbital nerve blockade for the preventive treatment of migraine: a single-blind, randomized, placebo-controlled study. Curr Med Res Opin. 2019 May;35(5):909-915.

Palamar Deniz, Uluduz Derya, Saip Sabahattin, et al. Ultrasound-guided greater occipital nerve block: an efficient technique in chronic refractory migraine without aura? Pain Physician 2015; 18:153-162.

Pisapia JM, Bhowmick DA, Farber RE, et al. Salvage C2 ganglionectomy after C2 nerve root decompression provides similar pain relief as a single surgical procedure for intractable occipital neuralgia. World Neurosurg. 2012;77(2):362-369.

Pohl H, Moisa M, Jung HH, et al. Long-term effects of self-administered transcranial direct current stimulation in episodic migraine prevention: results of a randomized controlled trial. Neuromodulation. 2021 Jul;24(5):890-898.

Refractory Occipital Neuralgia: Congress of Neurological Surgeons Systematic Review and Evidence-Based Guideline. Neurosurgery 77:332–341, 2015.

Robbins MS, Starling AJ, Pringsheim TM, et al. Treatment of cluster headache: The American Headache Society Evidence-Based Guidelines. Headache. 2016 Jul;56(7):1093-106.

Robinson IS, Salibian AA, Alfonso AR, et al. Surgical management of occipital neuralgia: a systematic review of the literature. Ann Plast Surg. 2021 Mar 1;86(3S Suppl 2):S322-S331.

Rodrigo D, Acín P, and Bermejo P. Occipital nerve stimulation for refractory chronic migraine: results of a long-term prospective study. Pain Physician 2017; 20:E151-E159.

Shauly O, Gould DJ, Sahai-Srivastava S, et al. Greater occipital nerve block for the treatment of chronic migraine headaches: a systematic review and meta-analysis. Plast Reconstr Surg. 2019 Oct;144(4):943-952.

Suer M, Wahezi SE, Abd-Elsayed A, et al. Cervical facet joint pain and cervicogenic headache treated with radiofrequency ablation: a systematic review. Pain Physician. 2022 May;25(3):251-263.

Taber's Cyclopedic Medical Dictionary. Ed. 23. Philadelphia: F.A. Davis Company. 2017.

Tang Y, Kang J, Zhang Y, et al. Influence of greater occipital nerve block on pain severity in migraine patients: a systematic review and meta-analysis. Am J Emerg Med. 2017 Nov;35(11):1750-1754.

Tao H, Wang T, Dong X, et al. Effectiveness of transcutaneous electrical nerve stimulation for the treatment of migraine: a meta-analysis of randomized controlled trials. The Journal of Headache and Pain (2018) 19:42.

Tepper SJ, Grosberg B, Daniel O, et al. Migraine treatment with external concurrent occipital and trigeminal neurostimulation-a randomized controlled trial. Headache. 2022 Sep;62(8):989-1001.

Tepper SJ, Rabany L, Cowan RP, et al. Remote electrical neuromodulation for migraine prevention: a double-blind, randomized, placebo-controlled clinical trial. Headache. 2023 Jan 27.

~~Vadivelu S, Bolognese P, Milhorat TH, et al. Occipital neuromodulation for refractory headache in the Chiari malformation population. Prog Neurol Surg. 2011;24:118-25.~~

~~Vanelderen P, Rouwette T, De Vooght P et al. Pulsed radiofrequency for the treatment of occipital neuralgia: a prospective study with 6 months of follow-up. Reg Anesth Pain Med. 2010 Mar-Apr;35(2):148-51.~~

Velásquez-Rimachi V, Chachaima-Mar J, Cárdenas-Baltazar EC, et al. Greater occipital nerve block for chronic migraine patients: a meta-analysis. Acta Neurol Scand. 2022 Aug;146(2):101-114.

Vincent AJPE, van Hoogstraten WS, Maassen Van Den Brink A, et al. Extracranial trigger site surgery for migraine: a systematic review with meta-analysis on elimination of headache symptoms. Front Neurol. 2019;10:89.

Voigt CL, Murphy MO. Occipital nerve blocks in the treatment of headaches: safety and efficacy. J Emerg Med. 2015 Jan;48(1):115-29.

~~Weibelt S, Andress,-Rothrock D, King W, et al. Suboccipital nerve blocks for suppression of chronic migraine: safety, efficacy, and predictors of outcome. Headache. 2010 Jun;50(6):1041-4.~~

Yang Y, Song M, Fan Y, et al. Occipital nerve stimulation for migraine: a systematic review. Pain Pract. 2016 Apr;16(4):509-17.

Xu J, Sun Z, Wu J, et al. Peripheral nerve stimulation in pain management: a systematic review. Pain Physician. 2021 Mar;24(2):E131-E152.

Zhang H, Yang X, Lin Y, et al. The efficacy of greater occipital nerve block for the treatment of migraine: a systematic review and meta-analysis. Clinical Neurology and Neurosurgery 165 (2018) 129-133.

Policy History/Revision Information

Date	Summary of Changes
TBD	**Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS086LA.S

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies 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.