Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache)

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Instructions for Use

Table of Contents **Page**

Application 1
Coverage Rationale 1
Medical Records Documentation Used for Reviews 2
Definitions 2
Applicable Codes 2
Description of Services 3
Clinical Evidence 4
U.S. Food and Drug Administration 26
References 27
Policy History/Revision Information 32
Instructions for Use 32

Related Commercial/Individual Exchange Policies

- Ablative Treatment for Spinal Pain
- Botulinum Toxins A and B
- Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements
- Electrical Stimulation for the Treatment of Pain and Muscle RehabilitationVagus and External Trigeminal Nerve Stimulation

Community Plan Policy

- Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache)

Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

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 Headache, 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

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Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

Definitions

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

Migraine Disability Assessment Test (MIDAS): The MIDAS questionnaire is a tool that is used to measure the impact that headaches have on an individual's life. The information on the questionnaire is helpful for the primary care provider to determine the level of pain and disability caused by headaches and to find the best treatment. After the questionnaire is completed, the total number of days from questions 1 to 5 are added together.

MIDAS Grade	Definition	MIDAS Score
I	Little or No Disability	0-5
II	Mild Disability	6-10
III	Moderate Disability	11-20
IV	Severe Disability	21+

If the MIDAS score is 6 or more, discussion with a provider is necessary (National Headache Foundation, 2018).

Migraine-Specific Quality of Life Questionnaire (MSQ): The MSQ is a self-report measure that assesses the impact of migraine on three domains of quality of life: role functioning, emotional functioning, and social functioning. The MSQ consists of 14 items that are rated on a 6-point Likert scale, ranging from 1 (very poor) to 6 (very good). The MSQ has been widely used and proven effective in various languages and population samples (Giannouli et al., 2024).

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 the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

CPT Code	Description
1057T	Insertion or replacement of subcutaneous neurostimulator pulse generators, with tunneling of 4 electrode arrays, bilateral supraorbital and occipital nerves, including all interrogation, programming, and imaging guidance, when performed
1058T	Revision of implanted subcutaneous unilateral supraorbital and occipital neurostimulator system, including all interrogation, programming, and imaging guidance, when performed
1059T	Removal of implanted subcutaneous unilateral supraorbital and occipital neurostimulator system
1060T	Electronic analysis of implanted subcutaneous supraorbital-occipital neurostimulator pulse generator (e.g., frequency, amplitude, pulse width, leads, electrode configuration); with complex programming by physician or other qualified health care professional
1061T	Electronic analysis of implanted subcutaneous supraorbital-occipital neurostimulator pulse generator (e.g., frequency, amplitude, pulse width, leads, electrode configuration); with simple programming by physician or other qualified health care professional
63185	Laminectomy with rhizotomy; 1 or 2 segments

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CPT Code	Description
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, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64596	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array
64597	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; each additional electrode array (List separately in addition to code for primary procedure)
64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure)
64722	Decompression; unspecified nerve(s) (specify)
64744	Transection or avulsion of; greater occipital nerve
64771	Transection or avulsion of other cranial nerve, extradural
64999	Unlisted procedure, nervous system

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HCPCS Code	Description
A4540	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)

Description of Services

Cervicogenic Headache and occipital neuralgia are conditions for which diagnosis and treatment have been gradually refined over the last several years. This terminology refers to specific types of unilateral headaches that are thought to arise from impingement or entrapment of the occipital nerves and/or the upper spinal vertebrae. Compression and injury of the occipital nerves in the neck muscles 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 the diagnosis of these entities currently include those of the International Headache Society and the Cervicogenic Headache International Study Group.

Various treatments have been advocated for Cervicogenic Headache and occipital neuralgia. Oral analgesics and anti-inflammatory agents are effective for some individuals, but there is a population of individuals who do not experience pain relief with these medications. Local injections or nerve blocks, epidural steroid injections, radiofrequency ablation of the

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planum nuchae, electrical stimulation, Rhizotomy, ganglionectomy, nerve root decompression, discectomy, and spinal fusion have all been investigated in the treatment of headache and occipital neuralgia.

Since medications provide only temporary relief and may cause side effects, surgical treatments such as occipital Neurectomy and nerve decompression for migraine and other headaches have been developed as a potential means to permanently prevent or produce long-term remission 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 to inhibit the transmission of pain signals 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 ways: transcutaneously, percutaneously, and using implantable devices. Peripherally implanted nerve stimulation entails the placement of electrodes on or near a selected peripheral nerve. Targets for stimulation include occipital nerves, auriculotemporal nerves, supraorbital nerves, and sphenopalatine ganglia.

Clinical Evidence

Diagnostic and Therapeutic Greater Occipital Nerve Blocks

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

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

Sabet et al. (2025) conducted a systematic review and meta-analysis that evaluated the safety and efficacy of ultrasound-guided GONB (US-GONB) for chronic migraine; PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines and the PICOS framework were followed. Eligible studies included clinical trials or observational studies that enrolled individuals with migraine with or without aura, comparing US-GONB with pulsed radiofrequency (PRF), sphenopalatine ganglion (SPG) block, sham procedures, or other interventions. Six studies that included 344 individuals were analyzed, comprising four randomized controlled trials (RCTs), one nonrandomized trial, and one retrospective cohort, with the mean age ranging from 25.75 to 47.33 years. Meta-analyses were performed in RevMan 5.4 using weighted mean differences and 95% CIs under random-effects models. The primary outcomes were pain intensity and monthly headache days measured by visual analog scale (VAS) or numeric rating scales (NRSs); the secondary end points included headache attack duration, monthly analgesic use, and adverse events. Compared with sham, US-GONB significantly reduced pain intensity, monthly headache days, and analgesic use and showed comparable efficacy to PRF alone, greater benefit when combined with PRF, and generally lower efficacy than SPG; dizziness was the most frequent adverse event, with serious complications being rare. The authors concluded that US-GONB may represent an effective and well-tolerated option for chronic migraine when pharmacotherapy or landmark-guided blocks fail and showed meaningful benefits compared with sham and potential synergism when combined with PRF. There are limitations, including small sample sizes, methodological heterogeneity, a limited number of studies with heterogeneous comparators that restricted meta-analysis, and limited generalizability, as most studies were conducted in Turkey, with only one in Egypt; this highlights the need for larger, standardized RCTs to inform clinical guidelines.

Hayes (2025) produced an Evidence Analysis Research Brief that evaluated the use of trigeminal nerve block (TNB) for the treatment of trigeminal neuralgia. The assessment reviewed available peer-reviewed literature and found that there is sufficient published evidence to warrant evaluation of this intervention. However, definitive conclusions regarding safety and effectiveness cannot be drawn because the review was limited to abstracts and did not include full-text critical appraisal. Development of evidence-based conclusions requires comprehensive evaluation of full-text studies, which was not conducted for this report. The identified evidence base is limited in both quantity and methodological rigor and includes one RCT that compared TNB with placebo; one comparative study that evaluated TNB alone vs TNB combined with another treatment modality; and seven single-arm studies that evaluated treatment strategies guided by TNB. No systematic reviews or meta-analyses were identified. In total, nine published abstracts were included, consisting primarily of uncontrolled and preliminary study designs. The predominance of noncomparative evidence limits the ability to determine clinical effectiveness, durability of benefit, and comparative value relative to established treatments. The studies evaluated heterogeneous TNB techniques, including injections using various local anesthetics, corticosteroids, and neurolytic agents, as well as procedures performed in conjunction with or prior to radiofrequency thermocoagulation.

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This variability further limits the generalizability of findings and prevents identification of an optimal technique, agent, or treatment protocol. Two clinical practice guidelines or professional position statements were identified. Based on a full-text review, these sources provide weak or limited support for the use of TNB in the management of trigeminal neuralgia and reflect the ongoing uncertainty regarding the quality and consistency of the evidence. Continued monitoring of emerging literature and consideration of a comprehensive evidence appraisal may be warranted should TNB become a higher clinical or stakeholder priority.

Unal et al. (2024) conducted a prospective, single-blinded, randomized trial at Ankara University that compared repetitive GON and SPG blocks in adults aged 18 to 65 years who had episodic migraine (EM) unresponsive to at least one prophylactic treatment. Participants met *International Classification of Headache Disorders, Third Edition* (*ICHD-3*) criteria for EM and were excluded for chronic migraine, major psychiatric illness, pregnancy, or prior interventional headache procedures. Overall, 40 participants were randomized (20 per group), with analysis including 18 in the GON group and 19 in the SPG group after attrition. Blocks were administered weekly for 4 weeks and monthly for 2 months, and outcomes included headache intensity, duration, number of headache days, acute medication use, and Migraine Disability Assessment (MIDAS) scores. Statistical analyses used Mann-Whitney U, Friedman, and Wilcoxon tests, with a p value of < 0.05 considered significant. At 3 months, GON block produced greater reductions than SPG block in headache intensity (difference: 3.0 vs 0.0; $p < 0.001$), headache duration (20.0 vs 14.0 hours; $p = 0.022$), number of headache days (5.0 vs 2.0; $p < 0.001$), and MIDAS scores (13.0 vs 6.0; $p < 0.001$). The prespecified secondary end points included the number of days of nonsteroidal anti-inflammatory drug use and adverse effects. The authors concluded that repetitive GON and SPG blockade reduces headache duration, intensity, number of headache days, and need for acute medical treatment in individuals with EM, with GON block providing a superior effect. Additionally, both treatments are easy to apply, effective, and safe. There are limitations, including the small sample size chosen to control for missing data, selection bias, and dropouts; absence of a placebo-controlled design that may render the observed reduction in headache duration misleading; baseline differences between groups in headache characteristics and acute treatment use; and lack of assessment of prophylactic treatment failures, which may indicate differing treatment resistance between groups.

Hayes developed an evolving evidence review in 2025, updated in 2026 on the repetitive sphenopalatine ganglion (SPG) block for prevention of chronic migraine. The available evidence consists of a small number of poor- to fair-quality studies with heterogeneous treatment protocols and short-term follow-up (3–6 months). While some studies report short-term improvement from baseline, comparative effectiveness results are inconsistent, including no statistically significant benefit versus saline sham in an underpowered RCT and conflicting outcomes versus greater occipital nerve block. Safety data are limited, long-term efficacy has not been established, and current clinical practice guidelines provide weak or insufficient support. Therefore, this service does not meet medical necessity criteria.

In 2024, Hayes developed an evidence analysis research brief for sphenopalatine ganglion block for treatment of occipital neuralgia to summarize the volume of publications and determine if there is adequate published peer-reviewed literature to evaluate the evidence related to sphenopalatine ganglion block for treating occipital neuralgia. A review of the published literature identified insufficient evidence to evaluate the safety or effectiveness of sphenopalatine ganglion (SPG) block for the treatment of occipital neuralgia. No peer-reviewed clinical studies or abstracts specifically evaluating SPG block for occipital neuralgia were identified, and no ongoing clinical trials are registered. Available publications address SPG block for other headache indications and are not applicable to occipital neuralgia. Given the absence of condition-specific clinical evidence, this service is considered investigational and does not meet medical necessity criteria.

In a randomized, double-blinded, placebo-controlled, parallel-group trial (ANODYNE) of GONBs with methylprednisolone and lignocaine vs placebo, Chowdhury et al. (2024) assessed the efficacy and tolerability of GONB injections as a transitional preventative treatment for episodic cluster headaches (ECHs). The trial included participants with ECH who were diagnosed by the *ICHD-3* criteria from the ages of 18 to 65 years and had one or more attacks per 24 hours for 7 days before randomization (baseline). The participants with ECH were either not on preventative medications or on stable doses for at least 3 months. The participants with ECH were randomized to receive active GONB [2 mL methylprednisolone (80 mg) and 2 mL lignocaine (2%)] and placebo (4-mL saline injections). Prior to the administration of GONB, lignocaine jelly was applied to the skin to mask the effect of numbness following the GONB. The main end point evaluated was the average change in the frequency of weekly attacks from baseline to the fourth week. All participants who received at least one injection of GONB and had a follow-up for 1 week following the GONB were monitored for efficacy in a modified intention-to-treat population. The analysis of safety included treatment-emergent adverse effects (TEAEs) in all participants who received at least one dose of the investigational product. The change in weekly attack frequency from baseline to the fourth week was -11.1 in the active group vs -7.7 in the placebo group. The authors pointed out that TEAEs occurred in 18 of 20 participants (90%) who received the active drug and in 18 of 20 (90%) of those who received a placebo. The common TEAEs that were uncovered were local site bleeding and pain, which were mild and transient. No serious adverse events were reported. Although this trial has a robust study design that used International Headache Society (IHS)–recommended outcome measures, local lignocaine jelly application before GONB

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for masking, and inclusion of cranial autonomic symptoms, restlessness, and various patient-reported outcome measures in the secondary outcomes, limitations did exist as well. The limitations of the trial include the use of verapamil as a preventative, a relatively small sample size, and the trial being a single-center experience. However, the findings of the trial underscore the utility of GONB with methylprednisolone and lignocaine as a transitional preventative in individuals with ECH. The authors concluded that GONB with methylprednisolone and lignocaine reduced the weekly attack frequency from baseline to week 1 through week 4 in participants with ECH compared with placebo. Overall, GONB was well tolerated. To evaluate the efficacy in individuals with ECH further, a head-to-head study comparing GONB with oral prednisolone would be beneficial.

In a systematic review and meta-analysis, Li and Tang (2024) assessed the efficacy of GONB to treat acute migraines. Among four RCTs, 224 individuals were included in the meta-analysis that showed that when compared with a control intervention in acute migraine, GONB intervention could significantly reduce pain scores at 45 to 60 minutes and pain scores at 30 minutes. The intervention demonstrated no impact on pain scores at 0 to 15 minutes, sustained headache relief, or use of rescue medication. Limitations of the analysis include the small sample size, limited number of studies, and short follow-up time; additionally, the EM and persistent migraine were included in the analysis, which could have affected the efficacy assessment. The authors concluded that the intervention of GONB may be able to alleviate pain intensity for acute migraine, with an average reduction of pain scores at 30 to 60 minutes of approximately 2. (Friedman et al., 2020, and Korucu et al., 2018, are included in this systematic review.)

In 2024, Mustafa et al. conducted a systematic review and meta-analysis to assess the effectiveness of GONB in chronic migraine, focusing on the impact of local anesthetics compared with a placebo. Included in the review were case-controlled studies, cohort studies, and RCTs in adults with chronic migraine (adhering to the *ICHD-3*). The outcomes that were primarily measured were the frequency, duration, and intensity of headache, along with safety assessments. The results of the review demonstrated a remarkable reduction in intensity and frequency of headaches in the first and second months of treatment with GONB when using anesthetics compared with placebo. The adverse events reported did not differ significantly between the intervention and placebo groups. The limitations of the review are the small sample size; absence of sufficient data from recent trials, which prevented consideration of baseline characteristics and hindered the ability to perform meta-regression; and failure to account for pretreatment medications that the individuals may have taken during the procedure. Furthermore, the analysis did not address comorbidities specifically, which could potentially influence the safety of the procedure in those with various comorbidities. The authors concluded that the administration of GONB with local anesthetic leads to a notable reduction in the intensity and frequency of headaches compared with placebo while underscoring the effectiveness of GONB; this affirms its satisfactory safety profile. The analysis emphasized the safety and efficacy of GONB; however, cautious interpretation is advised due to the limited number of studies and relatively small sample size. Further research and future studies could delve into different aspects to provide a more comprehensive assessment of the safety profile of the procedure in diverse populations while exploring various drugs, frequencies, and treatment plans to enhance the robustness and applicability of GONB for the management of chronic migraine. (Cuadrado et al., 2017, Gul et al., 2017, Inan et al., 2015, Dilli et al., 2015, and Özer et al., 2019, are included in this review.)

A Hayes (2023a) Evidence Analysis Research Brief summarized the volume of publications to determine whether there is adequate published, peer-reviewed literature to evaluate the evidence related to GONB for the treatment of ON. The evidence analysis suggested that there is currently not enough published, peer-reviewed literature to evaluate the evidence related to GONB for treating ON in a full assessment.

Hayes (2023b) 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 newly published studies on local injection therapy for cervicogenic headache and ON. The new evidence consists of systematic reviews, with and without meta-analysis. There were no RCTs that evaluated the therapy or studies that evaluated treatment guided by the therapy. 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-blinded, placebo-controlled study, Chowdhury et al. explored the use of GONB for preventing chronic migraine. The trial consisted of a baseline period of 4 weeks. Participants with chronic migraine were randomly assigned 1:1 to the placebo. The participants obtained bilateral GONB every 4 weeks 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 end point was the change from baseline across weeks 9 to 12 in the average number of headaches and migraine days. The key secondary end point was achievement of a 50% reduction in headache days compared with baseline across weeks 9 to 12. Documentation and reporting of serious adverse events were conducted to evaluate safety. The average days with headache and migraine at baseline (±SD) were 23.4 ±4.4 and 15.6 ±5.7 in the active group and 22.6 ±5.0 and 14.6 ±4.6 in the placebo group, respectively. The active group had a considerable gain in least-squares mean reduction in the

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number of headaches and migraine days compared with the placebo group (-4.2 days, 95% CI, -7.5 to -0.8 days, p = 0.018 and -4.7 days, 95% CI, 7.7-1.7 days, p = 0.003, in that order). In the active group, 40.9% of participants reached a ≥ 50% reduction in headache days vs 9.1% of those receiving a placebo (p = 0.024). There were 64 mild and transient adverse events recorded in 16 participants in the active group and 15 in the placebo group, and no death or serious adverse events were reported. GONB every 4 weeks with 2% lidocaine for 12 weeks was superior to placebo in reducing the average number of headaches and migraine days in participants with chronic migraine and had a good tolerability profile. The study does not represent participants with a chronic migraine history of two to four preventive treatment failures, which limits the generalizability of the study results. More robust trials that include longer follow-up are necessary to decide whether to use GONB to prevent chronic migraines.

Evans et al. (2023b) conducted a systematic review and meta-analysis to investigate the change in headache severity and frequency following a nerve block of the occipital trigger site. RCTs that used injection treatments for headaches with pain or tenderness in the occipital scalp were included in the review (12 RCTs, with treatment in 586 individuals). Evaluations included pain severity; a score was given from 0 to 10, and headache frequency was reported as days per week. The results of the meta-analysis of pain severity, which compared nerve blocks to baseline, showed statistically significant reductions of 2.88 points at 5 to 20 minutes, 3.74 points at 1 to 6 weeks, and 1.07 points at 12 to 24 weeks. Meta-analyses of pain severity with nerve blocks compared with treatment groups of neurolysis, PRF, and botulinum toxin type A showed similar headache pain severity at 1 to 2 weeks and inferior improvements compared with the treatment groups after 2 weeks. Meta-analyses of headache frequency showed statistically significant reductions at the 1- to 6-week follow-ups compared with baseline and at 1 to 6 weeks with inactive control injections. The authors concluded that the severity and frequency of occipital headaches are reduced following occipital nerve blocks and can be used to predict the success of migraine surgery. However, future research should investigate the long-term outcomes of the sub compartmental injection technique, particularly for changes in headache frequency.

Gordon et al. (2023) conducted a systematic review to evaluate the effectiveness and safety profile of GONB in individuals with cluster headaches. The individuals included were those with a cluster headache diagnosis and who received corticosteroid and local anesthetic injections in the suboccipital region. The outcomes measured were changes in the frequency/severity/duration of attacks; proportion of individuals who responded to treatment; time to attack freedom from an attack; change in attack bout length; and/or the presence of adverse effects of GON blockade. The review found that every effectiveness study found a significant response in one or more of the frequency/severity/duration of attacks or the proportion of individuals who responded to the treatment (47.8%-100.0%). A higher injectate volume and use of concurrent prophylaxis may be associated with an increased likelihood of response. Methylprednisolone may have the best safety profile of the available corticosteroids. The limitations of this study include the lack of exclusion criteria for study design, inability to undertake a quantitative data synthesis, and methodological and reporting inconsistency between studies. The authors concluded that GON blockade is safe and effective for cluster headache prevention. Higher injectate volumes may improve the likelihood of response, and the possibility of serious adverse events may be reduced by using methylprednisolone.

Elsayed et al. (2023), as part of a double-blinded RCT, aimed to compare the pain-relieving effect between distal and proximal ultrasound-guided bilateral GONBs for postdural puncture headache (PDPH). This study included 50 participants with PDPH, who were randomized into two equal groups. Group D received an ultrasound-guided distal bilateral GONB (at the superior nuchal line level). Group p received an ultrasound-guided proximal bilateral GONB (at the second cervical vertebra level). Three milliliters of isobaric bupivacaine 0.5% and 4 mg dexamethasone were injected in both blocks. The study demonstrated a significant decrease in lying down and sitting NRS-11 at 10 minutes and 6, 12, 24, 36, and 48 hours after the intervention compared with before the intervention in both groups. Only sitting NRS-11 was significantly lower in group p than group D in all measurements after the intervention. The success rate (sitting NRS-11 < 4) at 24 hours was 60% in group D and 84% in group P, with an insignificant difference. The total 48-hour paracetamol and tramadol consumption were significantly lower in group p than in group D (p = 0.038 and 0.036, respectively). Transient cervicalgia occurred in 8% of each group. The limitations of the study include the small number of cases that proved the secondary outcomes, along with the absence of a control group. The authors concluded that ultrasound-guided proximal and distal GONBs were minimally invasive, simple, and effective ways to treat PDPH, with the superiority of proximal GONB in alleviating PDPH.

In a 2022 systematic review with meta-analysis, Velásquez-Rimachi et al. evaluated evidence and quality assessment of GONB local anesthetic alone or combined 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 with the placebo at a one-time point. The meta-analysis was performed with random-effects models and evaluated random errors with the trial sequential analysis (TSA), the risk of bias with the risk-of-bias tool, and the certainty of the evidence with GRADE (Grading of Recommendations Assessment, Development, and Evaluations). The review uncovered 2,864 studies that showed that GONB reduced the intensity of headaches at the end of the first month [mean

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difference (MD), -1.35; 95% CI, -2.12 to -0.59] and the second month (MD, -2.10; 95% CI, -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 days, 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 = 0.45). 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 with a placebo and that adding corticosteroids did not demonstrate any additional benefits. However, the quality of the evidence was deficient because of the substantial risk of bias and imprecision. Additionally, considering that the TSA was inconclusive, more extensive, more specific trials are necessary.

Malekian et al. (2022) conducted a randomized, double-blinded, placebo-controlled trial, in which participants with EMs without aura were randomized to triamcinolone or lidocaine, triamcinolone plus lidocaine, or saline groups. Participants were evaluated at baseline, 1 week, 2 weeks, and 4 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 analysis of variance measures revealed that the severity and duration reduced considerably after the greater occipital block ($p < 0.001$ and $p = 0.001$, respectively). No difference was shown among groups at any point during the study ($p > 0.05$). A considerable decrease in frequency compared with baseline ($p = 0.002$; $p = 0.019$) was noted in groups 2 and 3, with lidocaine as part of the injection in a paired sample t test. Reported side effects with an association with triamcinolone were seen in three participants. The authors concluded that GONB with a local anesthetic reduces the number of attacks in EM. No injection was better than the placebo regarding the duration and severity of the headaches. The trial uncovered that all four types of injections that were used effectively decreased the severity and duration of headaches in EM, 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 in participants receiving lidocaine alone or combined with triamcinolone compared with 0.9% saline injection or triamcinolone. Further studies that explore whether these results were caused by the compressive effect of injected solution or the placebo effect are necessary.

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

In a meta-analysis aimed at evaluating the therapeutic effectiveness of GONB against PDPH, Chang et al. (2021) reviewed seven studies (four RCTs and three non-RCTs) to determine the severity of pain at 24 hours post procedure. The authors defined intervention failure as repeated GONBs, the use of analgesics, or the need for an epidural blood patch. The secondary outcomes analyzed in this study included the impact of GONB on pain relief at 1 hour and 12 hours post procedure. Their meta-analysis included 275 adult individuals, and the sample sizes of the included studies ranged from 16 to 90 individuals. The authors found a moderate risk of bias among the non-RCT studies overall. They reported that the pooled results showed a lower mean pain score at 24 hours and at 1 hour and 12 hours post procedure. The analysis also showed that using GONB also decreased the risk of intervention failure. Limitations noted by the authors include the high heterogeneity among the study populations, difference in treatment provided to the control groups (placebo, bed rest, hydration, or oral analgesics), small number of RCTs available for analysis, and short-term follow-up of 24 hours. The authors concluded that their meta-analysis shows 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 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. The authors included seven studies: five observational studies and two non-RCTs, with a total of

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140 individuals. 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 VAS or the numeric pain rating scale. The monthly mean frequency of pain was 27 days at baseline and changed to 3.2 after 1 week, 2.4 after 2 weeks, 3.6 after 1.5 months, and 2.3 after 3.5 months. In five studies, the mean pain reduction ranged from 8.2 (at 2 weeks after the first block) to -0.1 (at 1 month after the third block). Three studies reported minor adverse events. The authors concluded that the limited available evidence suggests that GONBs effectively improve pain in individuals with cervicogenic headache, both as short-term and preventative treatment. The available studies were either observational, noncontrolled, or nonrandomized trials with low-level evidence. Larger and randomized studies are needed to confirm the efficacy of the procedure. (Lauretti et al., 2014, previously cited in this policy, is included in this study.)

Friedman et al. (2020) conducted an RCT to determine whether GONB was as effective as intravenous (IV) metoclopramide for migraine. A double-dummy, double-blinded, parallel-arm, noninferiority study was conducted in two emergency departments (EDs). Participants with 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-to-10 scale between time zero and 1 hour later. The secondary outcomes included sustained headache relief, defined as achieving and maintaining a headache level of mild or none for 48 hours, without the use of additional analgesic medication and rescue medication in the ED. During a 2.5-year study period, 99 participants were randomized, with 51 randomized to GONB and 48 to metoclopramide. Those who received the GONB had a mean improvement of 5.0, and those who received metoclopramide had a mean improvement of 6.1. Sustained headache relief was reported by 11 of 51 participants (22%) who received GONB and 18 of 47 participants (38%) who received metoclopramide. Of the 51 participants with GONB, 17 (33%) required rescue medication in the ED vs eight of 48 participants (17%) who received metoclopramide. An adverse event was reported by 16 of 51 participants (31%) who received GONB and 18 of 48 participants (38%) who received metoclopramide. The authors concluded that GONB with bupivacaine was less efficacious than IV metoclopramide for the first-line treatment of migraine in the ED (included in the 2024 systematic review by Li and Tang).

A 2019 Hayes Health Technology Assessment report focused on the efficacy and safety of GONB for the preventive treatment of chronic migraine headaches in individuals with an inadequate response to standard care. 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 the inclusion criteria was found regarding the benefit of chronic use of this therapy. There is a need for additional, larger, well-designed, controlled trials that include longer follow-up to adequately determine the optimal clinical role of GONB in the preventive treatment of chronic migraine. There was small or insufficient evidence for the use of GONB for the prevention of debilitating symptoms of EM or transformed migraine in adults 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 and uncovered one newly published study that met the inclusion criteria. Hayes did not change their rating, which is based on low-quality evidence that suggests that GONB with an injection of a local anesthetic is relatively safe and could improve most headache outcomes over the short term compared with placebo. The low rating reflects the heterogeneity in the populations of individuals 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, 2019; updated 2022).

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 and cervicogenic headache.

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

Nguyen et al. (2025) conducted a systematic review and meta-analysis following PRISMA 2020 guidelines and registered in PROSPERO (International Prospective Register of Systematic Reviews) to evaluate the effectiveness of occipital nerve decompression for occipital neuralgia. Eligible studies included patients diagnosed with occipital neuralgia who underwent

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greater or lesser occipital nerve decompression, with at least five participants per study, excluding non-surgical or non-neuralgia conditions. Twelve studies comprising 838 patients were analyzed using a random-effects meta-analysis with restricted maximum likelihood estimation, assessing pooled effects on pain frequency reduction and heterogeneity via Cochran Q, tau², and I² statistics. The primary outcome was reduction in pain frequency measured as days per month, showing a pooled estimate of 20.30 fewer pain days per month (95% CI: 16.53–24.08, p < 0.0001) after nerve decompression. High heterogeneity (I² = 97.21%) was observed, attributed to surgical variability and patient selection differences. Pre-specified secondary endpoints included pain intensity, headache duration, and overall headache burden. The authors concluded that nerve decompression surgery demonstrates compelling efficacy in reducing pain frequency, intensity, and duration in patients with occipital neuralgia and chronic headaches, supporting its role as an effective intervention for refractory cases. There are limitations, including the very high heterogeneity (p = 97.21%), likely arising from variability in surgical techniques, patient selection, and outcome assessment methods despite the strong pooled treatment effect.

In a 2024a Hayes Evidence Analysis Research Brief, neuroplasty for the treatment of ON was reviewed. The aim of the review was to summarize the volume of publications related to neuroplasty for treating ON and to determine if there is adequate published, peer-reviewed literature to conduct a full assessment of the evidence. Adequate published, peer-reviewed literature to evaluate the evidence was uncovered, although conclusions about the safety and effectiveness cannot be made in the report due to the lack of full text being reviewed. If this technology is found to be emerging, evolving, controversial, or disruptive or if it becomes a priority for consumers, then a full appraisal will be conducted. There were no RCTs or clinical studies that evaluated neuroplasty. There were six studies uncovered that evaluated the treatment guide by neuroplasty and one systematic review without a meta-analysis. There were no position statements or guidelines identified, which suggests that there is no or unclear support for using neuroplasty in individuals with ON. (Pietramaggiori and Scherer, 2023, is included in this review, and Li et al., 2012, and Choi et al., 2015, previously cited in this policy, are also included in this review.)

In 2023a, Evans et al. conducted a systematic review and meta-analysis to summarize the effect of migraine surgery on headaches, severity, frequency, and Migraine Headache Index (MHI) scores derived by multiplying migraine severity, frequency, and duration. Included in the review were clinical trials that studied the surgical treatment of headaches; the meta-analyses were performed on outcomes using a random-effects model and determined the pooled average change from baseline, when possible, to compare treatment with a control. Included in the review were 18 studies, with six RCTs, one clinical trial, and 11 controlled clinical trials that treated 1,143 individuals with pathologies, including migraine, occipital migraine, frontal migraine, occipital nerve triggered headache, frontal headache, ON, and cervicogenic headache. It was found that migraine surgery reduced the headache frequency at 1 year post operation by 13 days per month compared with baseline (I^2 = 0%), reduced headache severity at 8 weeks to 5 years post operation by 4.16 points on a 0-to-10 scale compared with baseline (I^2 = 53%), and reduced MHI at 1 to 5 years post operation by 83.1 points compared with baseline (I^2 = 2%). The limitations of the meta-analyses are the small number of studies that could be analyzed, including studies with a high risk of bias. The authors concluded that the migraine surgery supplied a clinically statistically significant reduction in headache frequency, severity, and MHI scores. Additional studies, including RCTs with a low risk of bias, should be performed to improve the precision of the outcome.

Goyal et al. (2022) performed a systematic review to evaluate various interventional treatments for cervicogenic headache and compare their relative efficacies. The final analysis consisted of 23 articles that were published between January 2001 and March 2021. Overall, 11 studies evaluated the effect of radiofrequency ablation (RFA); five evaluated occipital nerve blocks, two each for facet joint injections, and deep cervical plexus blocks, and 1 study each evaluated atlantoaxial (AA) joint injections, cervical epidural injection, and cryoneurolysis. Most of the studies reported pain reduction except 2 studies on RFA. The occipital nerve block (GON, lesser occipital nerve) showed only limited evidence, as most of the studies were noncontrolled 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 neurodestructive 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; heterogeneity of the inclusion/exclusion criteria and outcomes assessed among the studies; small sample sizes; 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 may be a reasonable option for cervicogenic headache 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 (included in the Hayes, 2023a, Evidence Analysis Research Brief).

Vincent et al. (2019) conducted a systematic review and meta-analysis to evaluate the proportion of individuals with migraine who reported elimination of migraine headache after migraine trigger site surgery and to determine whether

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surgery compared with sham or no surgery is more effective in the elimination of migraine headache. Overall, 627 individuals with a diagnosis of migraine, in adherence to the classification of the IHS, were included. The treatment consisted of one or more surgical procedures that involved the extracranial nerves and/or arteries, with outcome data available at a minimum of 6 months. A proportion of 0.38 of individuals (random-effects model; 95% CI, 0.30-0.46) experienced elimination of migraine headaches at 6 to 12 months of follow-up. Data from three RCTs were used, and the calculated odds ratio for 90% to 100% elimination of migraine headaches was 21.46 (random-effects model; 95% CI, 5.64-81.58) in individuals who received migraine surgery compared with sham or no surgery. The authors reported that migraine surgery leads to elimination of migraine headaches in 38% of individuals with migraines. However, more elaborate, randomized trials are needed that have transparent reporting of selection of individuals, medication use, and surgical procedures and that implement detailed and longer follow-up times.

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, is an effective treatment for headaches. The long-term efficacy of these procedures for headaches has not been established in well-designed clinical trials.

Jin et al. (2026) conducted a systematic review registered in PROSPERO under PRISMA 2020 guidelines that integrated clinical and anatomical evidence to evaluate the efficacy and mechanisms of minimally invasive treatments for cervicogenic headache. PubMed, Embase, Cochrane Library, and Web of Science were searched from January 2004 to May 2025 for English-language studies of clinically diagnosed individuals who received procedures such as nerve block, RFA, PRF, coblation, or steroid injection. Overall, 23 studies met inclusion criteria, including four RCTs, 13 cohort studies, one case-control study, and five anatomical studies. Data extraction and quality appraisal were independently performed by two reviewers using the Cochrane Risk of Bias tool and Newcastle-Ottawa Scale, with narrative synthesis due to heterogeneity. The primary outcome was pain improvement, which was measured by scales such as the VAS, NRS, or Izbicki scale or as the proportion achieving at least 50% pain reduction, showing consistent short-term pain relief and improved quality of life across interventions targeting the C1 to 2 dorsal root ganglion (DRG), C1 to 2 joint, cervical disc, deep cervical plexus, and GON. The prespecified secondary end points included functional disability, quality of life, sleep or headache impact, adverse events, guidance modality differences, and durability of treatment effect. The review concluded that cervicogenic headache arises from multiple interacting upper cervical structures and that anatomically guided interventions that target these regions, particularly with ultrasound guidance, may provide pain relief and functional improvement through individualized strategies. There are limitations, including substantial heterogeneity in treatment and intervention protocols, limited long-term and safety data, small sample sizes, variability in study design and diagnostic criteria, restricted English-only literature search, exclusion of nonrelevant or incomplete reports, limited anatomical evidence on cervicogenic headache mechanisms, and contradictions between lower cervical intervention effects and upper cervical anatomical findings, all of which constrain definitive conclusions and meta-analytic comparison.

In a 2025 evidence analysis, Hayes summarized the volume of publications to determine if there is adequate published, peer-reviewed literature to evaluate the evidence related to occipital nerve decompression for treating migraines. A review of the available literature identified insufficient evidence to adequately evaluate the safety or effectiveness of occipital nerve decompression for the treatment of migraine. Only two abstracts were identified, consisting of one single-arm study and one systematic review/meta-analysis, with no randomized controlled trials or comparator studies available. The evidence is limited to abstract-level data, lacks robust study design, and does not provide sufficient comparative or long-term outcomes. No ongoing clinical trials were identified. Given the limited quantity and quality of evidence, occipital nerve decompression for migraine is considered investigational and does not meet medical necessity criteria.

In a systematic review and meta-analysis, Alrahbeni et al. (2024) aimed to analyze surgical approaches for refractory or intractable migraines. The literature that was collected focused on studies related to migraines and surgical outcomes, clinical trials, or observational studies that included any surgical intervention for refractory or intractable migraines, emphasizing key outcomes such as reductions in the intensity of the migraine, MIDAS, and 50% MHI reduction rates. Overall, 11 studies were included in the systematic review, and a meta-analysis of four studies that involved 95 individuals overall showed a reduction in the average intensity of the migraine using occipital nerve stimulation (ONS). An average MIDAS score reduction of -52.3 was seen in three studies, involving 85 individuals, although this was not statistically significant. A substantial decrease in the average migraine intensity was seen with nerve decompression surgery (from 8.31 down to 4.06). The median MIDAS score dropped from 57 to 20, while two studies indicated a success rate of 40% to 82%, respectively, for achieving a 50% reduction in the migraine MHI through nerve decompression. Findings from two of the studies suggest that septorhinoplasty and sinus surgery effectively decreased the migraine intensity scores. The limitations of the study are that the inclusion criteria were restricted to articles published solely in English, and outcomes such as migraine intensity, MHI, and MIDAS were based on patient-reported outcomes. Limitations also included the study design; absence of direct statistical comparison between intervention and control groups, which limits the strength

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of the conclusions; and limited number of trials that were included in the analysis. The authors concluded that the evidence emphasizes the potential advantages of surgical interventions as a promising approach to managing intractable or refractory migraines; however, more robust, comprehensive research is necessary to refine and solidify the efficacy of the methods that aim for widespread benefits while considering cost-effectiveness. (Rodrigo et al., 2017, previously cited in this policy, is included in this review.)

In a Hayes (2024b) Evidence Analysis Research Brief, the volume of publications related to auriculotemporal nerve decompression (ATN) for treating migraine was evaluated. Through a review of abstracts, it was determined that there is not enough published, peer-reviewed literature to evaluate the evidence in a full assessment. There were no RCTs identified. There was one study found that evaluated ATN decompression that compared ATN sparing vs ATN and superficial temporal artery sparing resection. One study that evaluated treatment guided by nerve decompression was identified, along with a systematic review without a meta-analysis. There were no position statements or guidelines identified that suggested no or unclear support for the use of ATN decompression for treating migraine headache. (Pietramaggiori and Scherer, 2023, and Baldelli et al., 2020, are included in this analysis.)

Hayes (2024c) conducted an Evidence Analysis Research Brief to summarize the volume of publications related to supratrochlear or SON decompression for treating migraine headache to determine if there is adequate published, peer-reviewed literature to evaluate the evidence in a full assessment. Through a review of abstracts, it was determined that there is adequate published, peer-reviewed literature, although conclusions about safety and effectiveness cannot be made in the report due to the lack of a full-text review. If supratrochlear or SON decompression becomes emerging, evolving, controversial, or disruptive, a full assessment will likely be completed. There were no RCTs identified. There were two studies found that evaluated supratrochlear or SON decompression that compared glabellar myectomy alone vs combined with supraorbital foraminotomy or front, occipital, or temporal trigger site decompression identified. Also, three studies were uncovered that evaluated the treatment guided by supratrochlear or SON decompression, although no position statements or guidelines were identified that suggested no or unclear support for the treatment. The evidence that was uncovered consisted of two comparative studies, three single-arm studies, and one systematic review with a meta-analysis. (Jose et al., 2018, previously cited in this policy, is included in this review.)

In the 2023 literature analysis by Pietramaggiori and Scherer, the authors described a minimally invasive nerve- and muscle-sparing technique to decompress the occipital nerves. The outcomes measured were the migraine days per month, use of medications, pain evaluation, and decrease in MHI analyzed by a retrospective chart review, which included 87 individuals who underwent nerve- and muscle-sparing surgical decompression of the greater and lesser monolateral or bilateral occipital nerves; individuals were followed up for 12 months. The review showed that surgical decompression significantly reduced ON burden (at least 50% improvement) in 91% of individuals, with 45% reporting a complete remission of occipital pain. Days with pain per month decreased by 80%, chronic background pain intensity decreased by 81%, and pain intensity during crisis decreased by 76%. Accordingly, drug use dropped by approximately 70%. The authors concluded that a surgical technique could contribute to and support surgical decompression as the first option among the invasive approaches to treat ON. The results of the analysis corroborate previous findings [included in the Hayes (2024a) Evidence Analysis Brief on neuroplasty treatment for ON and the Hayes (2024b) Evidence Analysis Brief on auriculotemporal nerve decompression for treatment of migraine headache].

McNutt et al. (2020) conducted a systematic review of 12 articles (including Pisapia et al., 2012, Ducic et al., 2009, Choi et al., 2015, Jose et al., 2018, and Li et al., 2012, below) that directly addressed the question of neurolysis vs neurectomy for the treatment of 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 seven observational studies and five single case reports. No RCTs 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 individuals in the analysis, with follow-up between 2 months and 5.6 years. Their analysis showed that individuals had a positive outcome when they had a positive response to GONB or Botox, had tenderness over the GON, 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 used various inclusion and exclusion criteria as well as outcome measures. Other limitations included the number of case reports, lack of a comparison group in many studies, high dropout rates, small sample sizes, lack of blinding, and lack of correlating outcomes to a particular surgical treatment. After reviewing the data, the authors found that there were conflicting results for neurolysis and no consistent outcome identified for neurectomy. They found that many individuals had concomitant headache diagnoses and additional confabulators and were not screened for other causes of occipital headache. The authors determined that there was insufficient evidence to recommend one treatment method over the other. The authors stated that higher-quality studies, including RCTs, are needed to evaluate these surgical options.

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A systematic review and meta-analysis was conducted by Baldelli et al. (2020). The nine selected studies included seven retrospective studies (four case-control; three case series), one blinded randomized controlled clinical trial, and one prospective cohort study. Overall, 1,135 individuals were included in studies of occipital nerve decompression that incorporated different surgical techniques. The sample size of each study ranged from 11 to 476. Surgical outcome was measured with the migraine headache questionnaire, percentage of postoperative pain relief, and the MHI. Follow-up was at least 6 months in each study. A 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; however, other RCTs are necessary to definitively confirm the findings. A main limitation is the retrospective nature of most of the studies. [Ducic et al., 2009, and Guyuron et al., 2009, previously cited in this policy, are included in this study; included in the Hayes (2024) Evidence Analysis Research Brief on auriculotemporal nerve decompression.]

Radiofrequency Ablation

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

Hayes (2023; updated 2025) developed a Health Technology Assessment to evaluate the effectiveness and safety of PRF compared with those of alternative treatments to treat postherpetic neuralgia in adults. A low-quality body of evidence suggests that PRF may provide short-term pain reduction and decreased medication use in adults with postherpetic neuralgia compared with baseline and sham therapy; however, the evidence is limited by study heterogeneity, variable treatment protocols, small sample sizes, and lack of long-term follow-up. Comparative data are sparse and inconsistent, with conflicting results vs spinal cord stimulation (SCS) and limited single-study comparisons with other interventions. PRF devices lack a regulatory indication for the treatment of postherpetic neuralgia, and clinical practice guidelines provide only weak or no support. Given the uncertainty regarding comparative effectiveness, durability of benefit, and selection criteria for individuals, PRF does not meet medical necessity criteria at this time.

Ertilav et al. (2024) conducted an RCT to compare the efficacy of repeated GONB and PRF therapy in participants with chronic migraine. To carry out the trial, the authors included 70 participants who were admitted to a neurology and algology outpatient clinic between September 2023 and December 2023 and diagnosed with chronic migraine according to the *ICHD-3* criteria. The participants were randomized into two groups to receive ultrasound-guided repeated GONB and PRF. The outcomes measured were recorded before the procedure and at the first and sixth months after the procedure. In both groups (35 with GONB and 32 with GONB PRF), the pain scores at the first and sixth month post procedure were significantly lower compared with those before the procedure. The VAS scores were significantly lower in the PRF group more than in the GONB group at the sixth month. In both groups, the postprocedural MIDAS scores at the first and sixth months were significantly lower compared with those before the procedure. In the GONB PRF group, MIDAS scores at the sixth month were significantly lower than MIDAS scores at the first month. The MIDAS scores were significantly lower in the PRF group than those in the GONB group at 6 months. The limitations of the study were the small sample size and absence of blinding of participants, which may reduce the reliability of the results due to the placebo effect. The authors concluded that the interventional procedures such as GONB and PRF are safe and effective methods for chronic migraines when many medical treatments are unresponsive. The authors noted that when applied with the right techniques, PRF and GONB for treating migraines is effective for appropriate individuals. It was also determined that PRF is an effective and safe option for long-term pain relief in chronic migraines and is a better alternative to GONB, for which the effectiveness is known.

Through an updated systematic review by Jain et al. (2024), the authors aimed to investigate the primary and secondary outcomes of RFA for chronic headache pain. The review resulted in a total of 580 articles found, and 32 were used and included in the review. The studies primarily focused on pain scores, duration of relief, function, and individuals' satisfaction. RFA was used to target various nerves as the pain generator and compared with other modalities such as local anesthetic or a corticosteroid in several studies. The limitations of the review include the retrospective nature of the studies and lack of consistency of approach and targeted nerves. The authors concluded that in all, RFA showed favorable outcomes in managing chronic headache pain. It was determined that RFA can serve as an alternative treatment option in individuals who experience failure of other conservative treatment regimens. All the included studies showed positive outcomes toward RFA for managing headache. To provide individuals and clinicians with evidence for the most appropriate treatment strategies, understanding the outcomes of RFA for headache pain is necessary. Further studies are necessary to establish an RFA treatment protocol for headache and provide clinicians with stronger strategies for treatment. Additionally, larger RCT studies are necessary to analyze the efficacy and safety of RFA in individuals with chronic headaches. (Fang et al., 2016, Guo et al., 2021, and Lee et al., 2020, are included in this review.)

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Saraçoğlu et al. (2024) conducted a double-blinded RCT that was aimed at evaluating the effects of combining PRF therapy with GONB therapy in participants with chronic migraine. The participants were divided into two groups: the GONB group and the GONB and PRF group. Each group consisted of 16 participants with chronic migraine. Using 0.5-Hz sensorial stimulation, a 5-cm-long radiofrequency needle was inserted with ultrasound guidance in both groups. Subsequently, all participants received GONB with 2 mL of 0.25% bupivacaine. In the GONB and PRF group, participants underwent 4 minutes of PRF at 42 °C, whereas the GONB group did not receive any PRF treatment (PRFT). Follow-up examinations were performed at 1, 2, 3, and 6 months after the procedure to evaluate the frequency and severity of migraine attacks, number of headache days, and analgesic consumption. The trial results showed that in the GONB and PRF group, VAS score, number of migraine attacks, number of headache days, and analgesic consumption were significantly lower than those in the GONB group. Significant decreases (60%) in mean VAS scores, number of migraine attacks, number of headache days, and consumption of analgesic medications were observed in the GONB and PRF group at the 1-, 2-, 3-, and 6-month follow-ups compared with the pretreatment period. The limitations of the study included the lack of assessment of quality of life, disability, and headache impact and the sole focus on the clinical effects of combining GONB for PRF in those participants with chronic migraine. The authors concluded that the combination of GONB with PRF is a promising new treatment option for individuals with chronic migraine. The approach has demonstrated efficiency in minimizing analgesic use, decreasing the frequency of migraine attacks, reducing the number of headache days, and decreasing the severity of migraine attacks.

Abd-Elsayed et al. (2024) retrospectively assessed the efficacy of RFA therapy for treating ON and headaches at health clinics throughout the United States. They hypothesized that RFA is a minimally invasive treatment that provides significant, long-term pain relief for ON and associated headaches. The retrospective analysis study data were collected from 277 patients who underwent occipital nerve RFA and had adequate preprocedure and postprocedure follow-up for data analysis. The data collected included the patients' age, sex, body mass index, headache diagnosis, pre- and postprocedure pain score using the VAS, improvement in symptoms through subjective percentage, and duration of symptom relief. The results of the assessment showed that the mean preprocedure pain score before RFA therapy in those who completed at least 6 months of follow-up was 5.57 (SD, 1.87), and the mean postprocedure pain score after RFA therapy was 2.39 (SD, 2.42). The improvement in pain scores prior to the procedure to post procedure was statistically significant, with a p value of < 0.001. The mean patient-reported percentage improvement in pain following RFA therapy was 63.53% (SD, 36.37). The mean duration of pain improvement was 253.9 days after the initiation of treatment (SD, 300.5). When patients who did not have any relief following their RFA procedure were included, the average preprocedure pain score was 5.54 (SD, 1.81), and the postprocedure pain score was 1.71 (SD, 1.81), with a p value of < 0.001. The limitations of the study include the retrospective nature of the study and limited data for collection. The authors concluded through the study that the minimally invasive, safe, and effective RFA is for individuals with refractory ONs and headaches. More studies are needed to illuminate the ideal individual characteristics for RFA treatment and the potential for procedural complications and long-term side effects that are associated with occipital nerve RFA therapy.

In a Hayes (2023c) Evidence Analysis Research Brief on nonpulsed (thermal) percutaneous RFA for treating ON, the volume of publications was summarized to determine whether there is adequate published, peer-reviewed literature to evaluate the evidence. The review of abstracts suggested that there currently is not enough published, peer-reviewed literature to evaluate the evidence in a full assessment. There were no RCTs or systematic reviews, no studies that evaluated nonpulsed (thermal) RFA, and one study that evaluated the treatment guided by nonpulsed (thermal) RFA.

In 2022, Suer et al. conducted a systematic review that evaluated 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 risk of bias. The primary outcome measures were pain relief and duration of relief, with successful relief ranging from 30% to 50%. The 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 reported that cervical facet RFA demonstrated efficacy in the treatment of 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 RFA for headaches, including pain outcome measures, secondary outcomes, and complications. Overall, 18 studies, which were composed of six RCTs, six prospective studies, and six retrospective studies, were included in the review. All the studies assessed pain improvement with RFA in individuals with headaches. 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

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headaches. Outcomes varied based on the difference in approaches regarding continuous radiofrequency vs PRF, temperature, and duration of administration. Most studies discussed in the review indicate a therapeutic benefit of RFA for headaches in a short-term period. The authors concluded that pain outcomes beyond 1 year are understudied, and further studies are needed to determine the long-term effects of RFA for headaches. Limitations include large variability in definitions of trigeminal neuralgia, radiofrequency technique, and 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 RFA (LTPRA) of the SPG in treating chronic cluster headache and ECH. Overall, 76 patients who were treated with LTPRA between January 2015 and October 2017 were reviewed. In total, 50 patients had ECH, and the remaining 26 had chronic cluster headache. The primary outcomes were clinical improvement rate, defined as the percentage of partial and complete pain relief results at 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 those with chronic cluster headache and 73.1%, 84%, and 68% in those with ECH at each follow-up time point, respectively. Three patients with chronic cluster headache and seven patients with ECH experienced no pain relief after the operation. Drooping eyelids were found in two cases; one recovered at the 3-month follow-up, but another one did not in the 24-month follow-up. No serious complications occurred intraoperatively or post operation. The authors concluded that LTPRA can be considered an effective and alternative surgical modality for treating patients with chronic cluster headache and ECH based on SPG block. Further research that includes RCTs is needed to validate these findings (included in the 2024 systematic review by Jain et al.).

Robinson et al. (2021) conducted a systematic review to summarize the current state of surgical ON management. Overall, 22 studies met the inclusion criteria, with a total of 766 individuals. In total, 15 studies evaluated interventions on the GON and/or lesser occipital nerve, and 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, individuals' satisfaction, quality of life, and analgesic usage. The average 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 RFA and cryoablation, found an overall success rate of 85%, with an average VAS score decrease from 7.4 ±1.7 to 2.9 ±1.7. The authors found that C2 ganglion decompression led to therapeutic success, as defined by a > 50% reduction in patient-reported preoperative pain without analgesia use, in 70% of individuals at the 2.5-year follow-up. Cervical dorsal rhizotomy provided full pain relief in 64% of individuals, partial relief in 20%, and no relief in 16% at the 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 risk of bias in most of the articles. (Acar et al., 2008, Blake et al., 2019, Choi et al., 2015, Gande et al., 2016, Jose et al., 2018, Keifer et al., 2017, Li et al., 2012, and Pisapia et al., 2012, previously cited in this policy, are included in this study.)

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 headaches or ON. No well-designed RCTs in the medical literature compare neurostimulation with established treatment options or a sham procedure. Studies in larger populations that include longer follow-up are needed to establish the benefits of neurostimulation and electrical stimulation for treating these conditions.

Hayes (2025) developed an Evidence Analysis Research Brief to summarize the volume of publications and determine if there is adequate published, peer-reviewed literature to evaluate the evidence related to the CT-132 prescription digital therapeutic (Click Therapeutics Inc.) for preventing episodic migraine. A review of the available literature identified insufficient evidence to evaluate the safety or effectiveness of the CT-132 prescription digital therapeutic for the prevention of episodic migraine. No peer-reviewed clinical studies or abstracts that specifically evaluate CT-132 for this indication were identified, and no ongoing clinical trials are registered. While general migraine management guidelines and reviews discuss digital and behavioral interventions broadly, they do not provide evidence specific to CT-132. Given the absence of condition- and product-specific clinical evidence, this technology is considered investigational and does not meet medical necessity criteria at this time.

Hayes (2025) created an Evolving Evidence Review on Nerivio for treating acute migraine episodes in adults. The available evidence for the Nerivio remote electrical neuromodulation (REN) device for the acute treatment of migraine in adults consists of a small number of very poor- to fair-quality studies, including two RCTs that compared REN with sham and several noncomparative cohort studies with short-term outcome assessment. While studies demonstrated statistically significant improvements in pain relief and pain freedom at 2 hours compared with sham and generally favorable short-term safety, the overall evidence is limited by small sample sizes, lack of robust comparators, heterogeneity in study

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design, and minimal long-term efficacy data. Systematic reviews rely on the same limited trial data, and professional guidelines provide weak or mixed support. Given these limitations, the evidence base provides minimal support and does not establish clear medical necessity for REN for acute migraine treatment.

Hayes (2025; updated 2026) developed an Evolving Evidence Review on the SPRINT Peripheral Nerve Stimulation (PNS) system (SPR Therapeutics) for chronic pain. The evidence for the SPRINT PNS System for the treatment of chronic pain in adults includes a limited number of studies, consisting of one fair-quality RCT and two lower-quality single-arm studies, with short- to mid-term follow-up. Clinical studies report improvements in pain, function, and quality of life compared with baseline and statistically significant pain reduction vs sham in one trial; however, durability of benefit beyond a few months after device removal remains uncertain. Systematic review evidence is limited and based on low-certainty data. While professional guidelines provide generally supportive recommendations for temporary PNS, including SPRINT PNS, the overall clinical evidence base is small and heterogeneous. As a result, the evidence demonstrates potential benefit but remains limited with respect to long-term outcomes and comparative effectiveness.

Hayes (2021; updated 2024) developed an Evolving Evidence Review on external trigeminal nerve stimulation (CEFALY® Device) for the prevention of episodic migraine headaches. The evidence evaluating the CEFALY device for the prevention of episodic migraine includes a small number of clinical studies, with variable quality and limited consistency in comparative outcomes. While several studies reported reductions in migraine days, migraine attacks, and rescue medication use compared with baseline, evidence from randomized trials demonstrates mixed results vs sham and pharmacological comparators, with modest effect sizes. Systematic reviews are limited by reliance on one or two studies and provide minimal support. Professional guidelines generally support noninvasive neuromodulation as a treatment option for migraine but do not strongly or specifically endorse CEFALY. Overall, the evidence suggests potential benefit, with a favorable safety profile; however, limitations in study quality, consistency, and strength of comparative evidence constrain conclusions regarding medical necessity.

ECRI (2018; updated 2025) developed an Evidence Analysis for the SPRINT PNS System (SPR Therapeutics) for treating pain. The SPRINT PNS system is a temporary neuromodulation device that is intended for implantation for up to 60 days to provide sustained pain relief after explantation. Available evidence suggests that SPRINT PNS is generally safe and may result in clinically meaningful improvements in pain, quality of life, and physical function in individuals with chronic pain. However, comparative evidence is limited, with few RCTs, small sample sizes, heterogeneous populations of individuals, and differing comparators across studies. As a result, there is insufficient evidence to draw firm conclusions regarding the comparative safety and effectiveness of SPRINT PNS relative to other pain management interventions, and the overall evidence indicates potential benefit but limited comparative validation.

Kollenburg et al. (2024) conducted a systematic review to provide a comprehensive overview of the effectiveness, safety, mechanisms, and practical application of ONS for treating headache disorders. The overall response rate with ONS was 35.7% to 100%, 17% to 100%, and 63% to 100% in individuals with cluster headache, chronic migraine, and ON, respectively. Regarding the long-term effectivity in all groups, 41.6% to 88.0% of individuals remained responders after ≥ 18.3 months. The most frequently reported adverse events included lead migration/fracture (13%) and local pain (7.3%). Based on the authors' results, they concluded that ONS can be considered a safe and effective treatment for chronic, intractable headache disorders. To support more widespread application of ONS, additional research that includes larger sample sizes should be conducted. (Dodick et al., 2015, and Rodrigo et al., 2017, previously cited in this policy, are included in this systematic review.)

ECRI (2012; updated 2023) conducted an Evidence Analysis for implantable PNS devices for treating chronic pain. Implantable PNS devices are designed to provide minimally invasive treatment of chronic pain by delivering electrical impulses to affected peripheral nerves. The available evidence, including several systematic reviews and small randomized and nonrandomized studies, suggests that PNS may reduce pain and improve quality of life in some individuals compared with sham or no treatment, with an acceptable safety profile. However, the evidence base is limited by small sample sizes, heterogeneous pain conditions, short follow-up durations, and risk of bias, and no studies directly compare PNS with other chronic pain management modalities. As a result, while potential benefit has been demonstrated in select populations, the overall evidence is insufficient to establish comparative effectiveness or long-term outcomes, and additional high-quality trials are needed to define medical necessity.

In 2024, Perdecioğlu et al. conducted a single-blinded RCT to show the changes in pain severity and frequency per month in chronic migraine with noninvasive PRFT. The participants were those who were diagnosed with chronic migraine according to the *ICHD-3* beta diagnostic criteria. In 50% of the participants, PRF was applied for treatment, with transcutaneous electrodes to the GON trace. For the other 50%, a GONB was placed under ultrasound guidance. The MIDAS was administered to the participants, and those with scores of > 2 were included in the study. The pain intensity and frequency were evaluated using the VAS and headache diary, which were completed before and 4 weeks post

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treatment. The results of the trial showed that when both groups were compared, the pre- and posttreatment VAS scores and headache frequencies were similar. VAS scores and headache frequency decreased significantly after treatment in both groups when comparing the pre- and posttreatment values in the groups. The limitations of the study are that the mean values for determining the study population did not include headache-specific people. Also, the control group was not designed with sham electrodes; therefore, the placebo effect could not be excluded. The authors concluded that noninvasive PRFT is safe and effective for treating chronic migraine. The participants' pain and frequency decreased with noninvasive PRFT, like those in the GONB group. Further studies are needed to establish clear protocols for this easy-to-administer, comfortable, and safe treatment.

Oliveira et al. (2024) created a narrative systematic review to explore the effectiveness and safety of GON PRF neuromodulation (PRFN) for headaches. The primary end point that was measured was the change in headache intensity. The secondary outcomes that were measured were the effect on monthly headache frequency, mental and physical health, mood, sleep, analgesic consumption, and side effects. The results of the review demonstrate that PRFN provides significant analgesia and reduction of monthly headache frequency in chronic migraine from 3 to 6 months and significant pain relief for ON from 6 to 10 months. Mild adverse effects were reported in 3.1% of the cohort. A minority of studies reported on secondary outcomes. The limitations of this study include the small amount of high-quality, prospective RCTs that have evaluated this topic. Much of the included data for the review came from observational studies, with inherent risk of bias. Most of the studies did not include a control group. There is significant heterogeneity across studies, with large differences in terms of headache indication, intervention parameters, image guidance technique, and comparators that made interstudy comparison challenging. The authors concluded that there is a low-quality body of evidence that indicates an analgesic benefit of PRFN of GON for ON and chronic migraine, but PRFN's role in other headache types needs more investigation. The optimal PRFN target and settings remain unclear. High-quality RCTs are necessary to further explore the role of this intervention. (Lee et al., 2020, is included in this review.)

Through a systematic review, Finnern et al. (2023) sought to appraise the literature for the efficacy of cervical SCS (cSCS) for treating any intractable, chronic headache, including migraine headaches (with or without aura), cluster headache, tension headache, and other types of headaches. The primary outcomes measured were headache intensity and frequency and adverse effects. Overall, 16 studies, with 107 individuals, were included, with the findings of type of headache, cluster headache, trigeminal neuropathy, ON, posttraumatic headache, cervicogenic headache, short-lasting unilateral neuralgiform headache with automatic symptoms, and poststroke facial pain. The results showed that there was very low-quality evidence that cSCS is associated with a decrease in migraine headache frequency, migraine headache intensity, and trigeminal neuropathy intensity. The placement for cSCS leads ranged from C1 to C4. The authors concluded that promising data from observational studies showed that cSCS may help decrease the frequency and intensity of chronic, intractable headaches; however, future well-powered RCTs are needed.

Veilleux et al. (2023) performed a systematic review of the efficacy of ONS for treating trigeminal autonomic cephalalgias (TACs). The primary outcomes that were measured were a reduction in headache intensity, duration, and frequency; adverse event rate; and reduction in medication use. The data for those with short-lasting, unilateral, and neuralgiform headache attacks with conjunctival injection and tearing (SUNCT) and cranial autonomic symptoms (SUNA) were reported separately, and the risk of bias was assessed using the National Institutes of Health Quality Assessment Tools. Of the studies in 417 individuals, 14 published papers were included in the analysis, with an average reduction in headache intensity and duration of 26.2% and 31.4%, in that order. The average reduction in headache frequency was 50%, with a 61.2% reduction in the use of abortive medications and a 31.1% reduction in the use of prophylactic medicines. The mean decrease in headache intensity and duration in the SUNCT/SUNA cohort was 56.8% and 42.8%. The overall responder rate (RR), defined as a > 50% reduction in attack frequency, was 60.8% in the non-SUNCT/non-SUNA cohort and 66.7% in the SUNCT/SUNA cohort. Adverse events that required repeat surgery were reported in 33% of cases. Risk-of-bias assessment suggests that articles that were included in this review had reasonable internal validity. The limitations of the study include the heterogeneous nature of the study and the need for uniform diagnosis criteria of medically refractory TACs because the definition varied across the available literature. The authors concluded that ONS may be an effective surgical treatment in approximately two-thirds of individuals with medically refractory TACs.

In a 2023 prospective, double-blinded, randomized, placebo-controlled, multicenter clinical trial, Tepper et al. enrolled 248 participants to assess the clinical efficacy of REN for preventing migraine. Participants were randomized in a 1:1 ratio and observed for 4 weeks, with an 8-week, double-blinded intervention; participants received 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 end point 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 with 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

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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 those achieving a 50% reduction in moderate/severe headache days [51.6% (49 of 95) vs 35.7% (30 of 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 intention-to-treat 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 and is a much-needed nonpharmacological alternative, as a stand-alone preventive therapy or combined with pharmacological therapies, to further enhance preventive impact. 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 who were taking two or more preventatives [included in the Hayes (2024) Evolving Evidence Review].

In a 2022 randomized, sham-controlled, double-blinded, multicenter trial, Tepper et al. evaluated the efficacy and safety of concurrent noninvasive 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 group. Overall, 109 participants were treated for at least one migraine episode, with 50 in the active group and 59 in the sham group. The primary end point that was measured was the decrease in pain 2 hours subsequent to treatment initiation. The secondary end points were pain relief at 1 hour and freedom from the most bothersome symptom at 2 hours post treatment initiation. The exploratory end points consisted of freedom from the most painful symptom at 2 hours and sustained pain freedom 24 hours following treatment. Overall, 60% of contributors (30 of 50) in the active arm described pain relief at 2 hours after the start of the first eligible treatment (primary outcome) vs 37% (22 of 59) in the control arm (difference, 23%; 95% CI, 2%-41%; p = 0.018). Freedom from pain at 2 hours, without rescue medicine, was described by 46% of contributors (23 of 50) in the active arm and by 12% of participants (seven of 59) in the sham arm (p < 0.001). Freedom from pain 2 hours after the treatment and after 24 hours was described by 4.25 times more participants in the active arm [36% (18 of 50)] compared with the sham arm [8% (five of 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 participants who were free from pain and the most bothersome symptom 2 hours after the stimulation [47% (17 of 36) and 11% (five of 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 SCS in the treatment of refractory chronic migraine (rCM). Overall, 20 adults with rCM (mean number 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, RRs, the MIDAS, the Headache Impact Test-6, and Migraine-Specific Quality of Life Questionnaire, were captured up to 52 weeks after implantation. Compared with baseline, at 52 weeks post implantation, there was a reduction in mean monthly migraine days by 9.3 days (p < 0.001). Overall, 60% and 50% of participants obtained at least 30% and at least 50% reduction, respectively, in mean monthly migraine days. By week 52, 50% of participants' chronic pattern converted to an episodic pattern. The proportion of participants who were classified with severe headache-related disability on the Headache Impact Test-6 decreased from 100% to 60% at week 52. Meaningful improvements in headache-related quality of life, measured by the Migraine-Specific Quality of Life Questionnaire, were observed, with a mean gain of 24.9 ±23.1 points (p < 0.001) at 52 weeks. No unanticipated adverse device effects occurred. No participants required any additional device surgical revision. The authors concluded that 10-kHz SCS may be a safe and effective neurostimulation option for individuals with rCM, 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 that includes RCTs is needed to validate these findings (included in the Finnern et al., 2023, systematic review).

In 2021, Hayes conducted an Evolving Evidence Review on the Nerivio device (Theranica USA Inc) 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 that there needs to be more guidance on using Nerivio to manage acute migraine episodes. The review suggests that evidence that compares 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 to the current level of support from clinical studies to minimal support. Overall, there was no new evidence, with longer-term follow-up, or evidence that compared Nerivio with standard migraine care since the 2021 publication, leaving the conclusion of continued minimal support for the technology. In the 2024 update, there were eight

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newly published clinical studies, one systematic review with meta-analysis, and one new guideline that may meet the inclusion criteria set out in the report, which was published in 2021 and does not change the current level of support.

Joswig et al. (2021) performed a retrospective review in 96 patients with migraine, cervicogenic headache, cluster headache, neuropathic pain of the scalp, tension-type headache, and new daily, persistent headache who had undergone 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 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, 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 for 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 in those without a response ($p < 0.01$). Of the 56 people 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 patients (6.5%) had requested hardware explantation. Stage II complications included one infection (1.6%) and 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 with various chronic headache conditions. The study limitations included the retrospective nature, lack of controls who were receiving the placebo intervention, and randomization.

Pohl et al. (2021) completed an RCT to test the hypothesis that self-administered, anodal transcranial direct current stimulation (tDCS) over the visual cortex significantly decreases the number of monthly migraine days in EM. The study was single blinded, randomized, and sham controlled. The inclusion criteria were participants who were aged 18 to 80 years and had a diagnosis of EM. The exclusion criteria were pregnancy, a neurodegenerative disorder, a contraindication against magnetic resonance imaging examinations, and less than two migraine days during the 28-day baseline period. Participants whose baseline period suggested chronic migraine were excluded. After baseline, participants applied daily either verum (anodal-1 mA to 20 minutes) or sham tDCS (anodal-1 mA to 30 seconds) 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. Overall, 28 participants 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. In total, 23 datasets were taken for further analysis. Compared with 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 EM is safe and results in a lower number of 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 include the retrospective nature, lack of controls who received the placebo intervention, and classification of individual attacks being 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 PNS in managing acute or chronic pain was conducted by Xu et al. (2021). The review included 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 ONS on pain-modulatory mechanisms in the trigeminocervical area in participants with chronic migraine. In a balanced repeated-measurements design in eight participants 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 airflow was directed onto the cornea of the eye. The reflex response was recorded using a video camera, which detected eyelid closure frequency (documented as eyelid closures per minute). This method aimed to measure the antinociceptive protective mechanism of the orbicularis oculi reflex in a way as physiological as possible. At the same time, it allowed recording of 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 1-hour break between the two test runs. To rule out a sequence effect, the participants were randomized into two groups: one group (A) first went through the “on” phase measurement and, after a 1-hour break, the “off” phase measurement. In the second group (B),

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the “off” phase measurement was started, and the “on” phase measurement was carried out 1 hour later. The results showed the orbicularis oculi reflex in active ONS (7.38 ±20.14 eyelid closures/minute) compared with inactive ONS (18.73 ±14.30 eyelid closures/minute) to be reduced (p = 0.021). The authors concluded that this suggests that 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 that includes RCTs is needed to validate these findings.

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

A Hayes Health Technology Assessment report on ONS for chronic migraine headache identified eight studies that included four RCTs, of which two had a crossover design; one was an uncontrolled, open-label extension study of an RCT; and four were prospective uncontrolled studies. The sample size ranged from eight to 157 individuals, and follow-up ranged from 3 months to 9 years. In all but one study, individuals were selected for permanent ONS implantation based on a positive response to a temporary trial of ONS; this was typically a ≥ 50% reduction in pain that lasted for a few weeks. The most-reported outcome measures were the reduction in headache frequency and headache pain intensity. Other commonly reported outcome measures were response rate (most often defined as a ≥ 50% reduction in headache frequency and/or intensity) and/or a ≥ 30% reduction, headache-related disability, and quality of life. The report concluded that based on the available evidence, ONS appeared to have a positive but variable treatment effect on headache outcomes in selected individuals, 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 in improving headache outcomes in some individuals with chronic migraine. The update outlines how ONS is usually well tolerated; it may result in complications that require additional surgeries (Hayes, 2020a; updated 2022). (Dodick et al., 2015, and Rodrigo et al., 2017, previously cited in this policy, are included in this study.)

A Hayes Health Technology Assessment report focused on ONS for the treatment of chronic cluster headache that had failed to respond to available drug treatments. The evidence base for this report included one retrospective, comparative cohort study; four prospective or retrospective pretest/posttest studies; and two prospective case series that evaluated ONS for the treatment of individuals with chronic cluster headache (n = 15-67 individuals who were followed up for 3 months to 6.1 years). The reviewed studies did not provide sufficient evidence to evaluate the effectiveness of ONS for chronic cluster headache. Across the studies that evaluated ONS for the treatment of chronic cluster headache, individuals achieved a clinically meaningful ≥ 50% decrease in cluster headache attacks from baseline among 41% to 90% of those treated. Reduction in the intensity of pain during a cluster headache attack from baseline varied widely (range, 11%-96%) across studies, although 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 achieving a ≥ 50% decrease in cluster headache attacks from baseline in the DBS group compared with the ONS group (100% vs 41%). Reduction in pain intensity scores was greater in those receiving DBS than individuals receiving ONS (50% vs 11% reduction). Complications of ONS included uncomfortable or intolerable paresthesia (13%-35%), infection (2%-27%), pain or discomfort at the wound or implant site (3%-24%), hardware or stimulation dysfunction (19%), wire or electrode breakage or migration (2%-17%), neck stiffness (16%), need for a battery replacement < 1 year after implantation (12%), wire externalization or pressure ulcer due to a 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 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 six 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. 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

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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. In the 2023 update, there were three newly published studies; however, there was no change in the current rating of D2 for ONS for the treatment of debilitating, medically refractory cluster headaches in adult individuals (Hayes, 2020b; updated 2023). (Magis et al., 2011, and Miller et al., 2017, previously cited in this policy, are included in this study.)

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

Clinical Practice Guidelines

American Academy of Pain Medicine (AAPM) Foundation

The AAPM developed a multidisciplinary panel of eight physicians, two psychologists, and one person representative to review the multidisciplinary preventative options for migraine management in three categories: medications, behavioral, and interventional strategies. The panel concluded that 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 impairment, as defined by patient-related outcomes. 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 EM. 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 Headache Society (AHS)

Migraine is a common cause of ED visits due to headache, but the treatments offered in the ED can vary. This paper presents updated clinical practice guidelines for managing migraine attacks in the ED, which were informed by new clinical trial data that evaluated treatments for migraine attacks in the ED and were included in a rigorous review process. This updated review found that (1) IV prochlorperazine and GONBs had the strongest evidence and must be offered to patients in the ED; (2) several other treatments were found to be helpful and should be offered; and (3) IV opioids and IV paracetamol/acetaminophen are not recommended for migraine-related pain relief.

Prochlorperazine IV and GONB must be offered to eligible adults presenting to the ED with a migraine attack for the treatment of headache that requires parenteral therapy (level A; must offer) in those without contraindications, while hydromorphone IV must not be offered (level A; must not offer). Treatments that should be offered, when appropriate (level B; should offer), include dexketoprofen IV, ketorolac IV, metoclopramide IV, subcutaneous sumatriptan, and supraorbital nerve block. Chlorpromazine IV, dexamethasone IV, and valproate IV may be offered (level C; may offer). Paracetamol IV may not be offered (level C; should not offer). Eptinezumab should be offered (level B) only for patients who match the clinical trial population but is rated level U (no recommendation for an ED-specific population). Additional evidence is needed for caffeine, granisetron, ibuprofen, ketamine, lidocaine, normal saline, propofol, and SPG blocks, which are all currently rated as level U (no recommendation).

American Interventional Headache Society (AIHS)/American Society of Regional Anesthesia and Pain Medicine (ASRA)/American Society of Spine Radiology (ASSR)/ European Society of Regional Anaesthesia and Pain Therapy (ESRA)/Obstetric Anaesthetists' Association (OAA)/Society for Obstetric Anesthesia and Perinatology (SOAP)

In 2023, a multidisciplinary panel of 21 collaborators outlined recommendations for the prevention, identification, and management of PDPH, including the strength and certainty of evidence of various patient, procedural, diagnostic, and management aspects of PDPH.

- The efficacy of GONB for PDPH after dural puncture with wider-gauge needles was unclear (level of certainty: low).
- GONBs may be offered to those with PDPH after spinal anesthesia with a narrower-gauge (≤ 22 G) needle, although headache may recur in a substantial proportion of patients, with more severe headache requiring an epidural blood patch (evidence grade: C; level of certainty: moderate).

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Several interventional techniques, such as GONB or SPG blocks, are novel therapies that need more robust evidence (Uppal et al., 2023).

American Society of Anesthesiologists (ASA)

In their practice statement on PDPH, the ASA states that there is insufficient evidence to recommend the use of GONBs or SPG 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 ASA and ASRA state the following: “Subcutaneous PNS may be used in the multimodal treatment of individuals with painful peripheral nerve injuries who have not responded to other therapies” (ASA/ASRA, 2010).

American Headache Society (AHS)

In 2021, the AHS incorporated recent research findings, expert consensus, and patient perspectives into updated guidance on the use of new acute and preventive treatments for migraines in adults. The AHS indicates that all patients with a confirmed diagnosis of migraine may be offered treatment with a neuromodulatory device, which modulates pain mechanisms involved in headache by stimulating the nervous system centrally or peripherally with an electric current or a magnetic field. Although the efficacy and safety of neuromodulation are supported by positive results from multiple clinical trials, the use of neuromodulatory devices in clinical practice has been limited. Patients with an inadequate response to a migraine-specific medication and those with frequent attacks who may be at risk of developing medication-overuse headache and/or chronic migraine due to overuse of acute medication should be considered for a trial of a neuromodulatory device as an adjunct to the existing treatment plan (Ailani et al., 2021).

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 patients. Neuromodulation may be helpful for patients who prefer nondrug therapies, respond poorly, or 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. SPG 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), level C recommendation (positive study: warfarin; negative studies: cimetidine/chlorpheniramine, candesartan), or 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).

The AHS has issued a position 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 patients with migraine. According to the AHS, there are no convincing or definitive data, to date, that show its long-term value. Besides replacing the use of more appropriate treatments, surgical intervention also may produce side effects that are not reversible and carry the risks associated with any surgery (AHS, 2012).

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.”

American Society of Interventional Pain Physicians (ASIPP)/American Society of Regional Anesthesia and Pain Medicine (ASRA)/North American Spine Society (NASS)

In 2024, the ASIPP, the ASRA, and NASS developed recommendations for the use of corticosteroids for adult chronic pain interventions.

Safety of steroid injections in sympathetic nerve blocks:

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- Statements
  - Sympathetic blocks may provide pain relief, with or without the addition of corticosteroid in the injectate (moderate).
  - Use of particulate corticosteroids in stellate ganglion blocks may cause central nervous system injury (low).
  - Reported pain relief after stellate ganglion block is similar if performed under fluoroscopy or ultrasound guidance (moderate).
  - Image guidance may help decrease complications and improve accuracy of sympathetic blocks, including visceral sympathetic blocks (moderate).
- Recommendations
  - Local anesthetic alone is sufficient for performing sympathetic blocks for pain relief (C).
  - Imaging guidance with ultrasound or fluoroscopy is recommended for the performance of sympathetic blocks, with ultrasound permitting visualization of vascular structures (B).

Safety of corticosteroid injections in greater occipital nerve blocks:
- Statements
  - The proximal approach has only been described with an ultrasound technique. Image guidance may improve the efficacy of the distal approach to GONBs compared with a non–image-guided approach (low).
  - With ultrasound guidance, both the classic/distal approach and the proximal approach appear to be effective for GONBs (moderate).
  - The proximal approach may provide more sustained benefit than the distal approach (low).
  - The addition of corticosteroid to the local anesthetic improve outcomes compared with local anesthetic alone or saline when performing GONBs in patients with cluster headaches (moderate).
  - Local anesthetic alone yields similar outcomes compared with local anesthetic with corticosteroid when performing GONBs in patients with migraine and medication overuse headaches (moderate).
- Recommendations
  - Consider using ultrasound when performing GONBs. Clinicians may choose either the classic/distal or the proximal approach to GONB, but the latter should be performed with ultrasound guidance (A).
  - The addition of corticosteroid to the local anesthetic is preferred in GONBs for cluster headache (C).
  - Clinicians should avoid the use of corticosteroids in GONBs for migraine and medication overuse headache (D).
  - Clinicians should monitor and limit the number and frequency of GONBs with corticosteroids to avoid side effects (B).

American Society of Pain and Neuroscience (ASPN)

According to the Latest Evidence-Based Application for Radiofrequency Neurotomy (LEARN) best practice guidelines from the ASPN consensus statement, occipital neurotomy may be selectively offered for the treatment of ON pain when greater or lesser nerves have been identified as the etiology of pain via diagnostic blocks. GRADE II-2 C.

Best Practices Summary

- Use of occipital nerve radiofrequency neurotomy (RFN) is primarily for symptoms of ON that are causing posterior head pain and has also been described for use in migraine syndromes with occipital tenderness.
- Implementation of the IHS diagnostic criteria for ON is standard practice.
- Diagnostic blockade of the occipital nerves should precede the use of RFN.
- Before RFN of the occipital nerves, other possible etiologies should be ruled out through either magnetic resonance imaging and/or computed tomography imaging. Imaging is not itself a diagnostic for ON.
- Evidence best supports the use of PRFN over other RFN options. Time settings for lesion creation range from a single lesion at 90 seconds to up to three lesions for 120 seconds. Further studies are necessary to compare procedural techniques.
- Several studies have documented 6 months of pain relief. Longer follow-up periods are needed to recommend repeat sessions of RFN in successfully treated people.

(Lee et al., 2021)

Congress of Neurological Surgeons (CNS)

In 2023, the CNS Guidelines Task Force systematically reviewed the relevant literature on ONS for ON to update the original 2015 guidelines, ensuring timeliness and accuracy for clinical practice. This minor update includes the following recommendation: “Clinicians may use ONS as a treatment option for patients with medically refractory ON” (level III) (Staudt et al., 2023).

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The CNS published an evidence-based guideline in 2015 that supports the use of ONS as a treatment option for patients with medically refractory ON. The population in the nine studies that were reviewed was small, and there was a short duration of follow-up (Sweet, 2015). Class III evidence and level III recommendation (evidence from case series, comparative studies with historical controls, case reports, and expert opinion as well as significantly flawed RCTs).

Department of Veterans Affairs/Department of Defense (VA/DOD)

In the 2023 *VA/DOD Clinical Practice Guideline for Management of Headache*, the following recommendations for headache and/or migraine are made:

- There is insufficient evidence to recommend for or against any form of neuromodulation for the treatment and/or prevention of migraine:
  - Noninvasive vagus nerve stimulation
  - Supraorbital or external trigeminal nerve stimulation
  - Remote electrical neurostimulation
  - External combined occipital and trigeminal
  - Neurostimulation system
  - Repetitive transcranial magnetic stimulation
  - tDCS
- There is insufficient evidence to recommend for or against GONB for preventing chronic migraine (neither for nor against; reviewed, new added).
- We suggest against abobotulinumtoxin A or onabotulinumtoxin A injection to prevent EM.
- We suggest onabotulinumtoxin A injection for the prevention of chronic migraine.
- There is insufficient evidence to recommend for or against the following for headache:
  - Transcranial magnetic stimulation
  - tDCS
  - External trigeminal nerve stimulation
  - Supraorbital electrical stimulation
- We suggest onabotulinumtoxin A injection for the prevention of chronic migraine (weak for; reviewed, not changed).

A 2020 VA/DOD *Clinical Practice Guideline for the Primary Care Management of Headache* found that there is insufficient evidence to recommend for or against the following for headache:

- Transcranial magnetic stimulation
- tDCS
- PRF or SPG block
- External trigeminal nerve stimulation
- Supraorbital electrical stimulation
- Neuromodulation

European Academy of Neurology (EAN)

These guidelines provide evidence-based recommendations for the treatment of cluster headache.

- Steroids can be administered orally or as an infusion. Another approach is local nerve blocks, mainly of the GON, where cortisone is added.
- Pharmacological nerve block of the GON is recommended and can be repeated if efficacious.
- No recommendation for greater ONS, based on a very low level of evidence.

(May et al., 2023)

European Headache Federation (EHF)

In a set of recommendations regarding neuromodulation for chronic headaches, the EHF states that despite a growing field of stimulation devices in headache treatment, further controlled studies are warranted to validate, strengthen, and disseminate the use of neurostimulation. The EHF 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 that has 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, to evaluate the peer-reviewed literature, current research, and clinical experience and to give guidance for the appropriate use of these methods. The Neuromodulation Appropriateness Consensus Committee found that evidence supports

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extracranial stimulation for facial pain, migraine, and scalp pain but is limited for intracranial neuromodulation (Deer et al., 2014).

National Institute for Health and Care Excellence (NICE)

The 2022 NICE guidelines on transcutaneous electrical stimulation of the SON for treating and preventing migraine offered the following recommendations:

- Evidence on the safety of transcutaneous electrical stimulation of the SON for treating and preventing migraine is adequate and raises no major safety concerns. For efficacy:
  - The evidence for treating an acute migraine attack is adequate but, for treating subsequent attacks, is limited in quality and quantity. So, for treating acute migraine, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.
  - Find out what special arrangements mean on the NICE interventional procedures guidance page.
  - The evidence for preventing migraine is inadequate in quality. So, for preventing migraine, this procedure should only be used in the context of research.
- Clinicians wanting to do transcutaneous electrical stimulation of the SON for acute treatment of migraine should:
  - Inform the clinical governance leads in their health care organization.
  - Give people and their families and carers clear written information to support shared decision-making, including NICE's information for the public.
  - Ensure that people and their families and carers understand the procedure's safety and efficacy and any uncertainties about these.
  - Audit and review clinical outcomes in everyone who is having the procedure. The main efficacy and safety outcomes that are identified in this guidance can be entered into NICE's interventional procedures outcomes audit tool (for use at local discretion).
  - Discuss the outcomes of the procedure during their annual appraisal to reflect, learn, and improve.
- Health care organizations should:
  - Ensure that systems are in place that support clinicians to collect and report data on outcomes and safety for everyone who is having this procedure.
  - Regularly review data on outcomes and safety for this procedure.
- Patient selection should usually be done by clinicians (including clinical nurse specialists) with expertise in managing migraine.
- NICE encourages further research on transcutaneous electrical stimulation of the SON for treating and preventing migraine. Studies should describe clearly whether the procedure is used for treatment or prevention. They should include details of patient selection and the intensity, duration, and frequency of use. Outcome measures should include the number and severity of migraine episodes, quality of life in the short and long term, any changes in medication, and management of subsequent attacks. The development of any complications after starting treatment should be documented.
- The usual treatment options for migraines are medical therapies to either stop or prevent attacks (see NICE's guideline on headaches in over 12s). For acute migraine attacks, these include analgesics, triptans, and antiemetics. Treatments to stop or reduce the frequency of migraine attacks include β-blockers, calcium channel blockers, tricyclic antidepressants, antiepileptics, and calcitonin gene-related peptide inhibitors.
- Invasive treatments are reserved for people with distressing symptoms that are refractory to medical therapy. These include nerve blocks, botulinum toxin (see NICE's technology appraisal guidance on botulinum toxin type A for the prevention of headaches in adults with chronic migraine), acupuncture, and interventional procedures (see NICE's interventional procedures guidance on ONS, transcutaneous stimulation of the cervical branch of the vagus nerve, and transcranial magnetic stimulation).
- Transcutaneous electrical stimulation of the SON uses small electrical currents to stimulate the SONs (branches of the ophthalmic nerve, the first division of the trigeminal nerve) through the skin that is overlying the nerves. It is also called external trigeminal nerve stimulation or eTNS. The aim is to relieve headache and, when used regularly, to reduce the severity and the frequency of migraine attacks. People with migraine administer the therapy themselves using a small, battery-operated device. For example, one device consists of a headband with a central button connected to a self-adhesive electrode patch. This is applied to the forehead above the eyebrows. When the device is activated, small electrical impulses stimulate the SONs (branches of the ophthalmic nerve, the first division of the trigeminal nerve). The intensity of the electrical pulses increases periodically and can be self-adjusted. Stimulation is applied daily for approximately 1 to 2 hours during an acute migraine attack and for 20 minutes for prevention between attacks.
- NICE conducted a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 14 sources, which was discussed by the committee. The evidence included two RCTs, three case series, and one observational survey for the acute treatment of migraine. It included four RCTs, two case series, one observational survey, and one U.S. Food and Drug

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Administration Manufacturer and User Facility Device Experience Database adverse event report for prevention. It is presented in the Summary of Key Evidence section in the Interventional Procedures Overview. Other relevant literature is in the appendix of the overview.

- The professional experts and the committee considered the key efficacy outcomes to be reduced frequency, duration, and severity of migraine episodes; reduced medication use; and improved quality of life.
- The professional experts and the committee considered the key safety outcomes to be pain, weakness, poststimulation headaches, and worsening of migraine.
- Twelve commentaries from people who have had this procedure and a submission from a patient organization were discussed by the committee.
- The committee noted that migraine is often a chronic condition, with a detrimental effect on quality of life. It recognized that for some people, there is a lack of effective prevention and treatment options.
- The committee noted that many people who have had this procedure continued to take medications to treat or prevent migraine.
- The committee was pleased to receive patients' commentary and a submission from a patient organization for this procedure. It noted that several people reported a negative experience of the procedure, including unpleasant side effects.

In the updated 2021 NICE clinical guideline on headaches in over 12s, diagnosis and management of cluster headache and treatment were addressed. The recommendations include:

- Discuss the need for neuroimaging in people with a first bout of cluster headache with a general practitioner who has a special interest in headache or a neurologist (2012).
- Offer oxygen and/or subcutaneous or nasal triptan for the acute treatment of cluster headache (2012). In November 2015, this was an off-label use of subcutaneous triptans in under 18s. Nasal triptans did not have a UK marketing authorization for this indication.
- When using oxygen for the acute treatment of cluster headache:
  - Use 100% oxygen at a flow rate of at least 12 liters per minute with a nonrebreathing mask and a reservoir bag; and
  - Arrange provision of home and ambulatory oxygen (2012).
- When using a subcutaneous or nasal triptan, ensure that the person is offered an adequate supply of triptans, calculated according to their history of cluster bouts, based on the manufacturer's maximum daily dose (2012). In November 2015, this was an off-label use of subcutaneous triptans in under 18s. Nasal triptans did not have a UK marketing authorization for this indication. See NICE's information on prescribing medicines.
- Do not offer paracetamol, nonsteirodal anti-inflammatory drugs, opioids, ergots, or oral triptans for the acute treatment of cluster headache (2012).

A 2015 NICE guideline for the implantation of an SPG stimulation device for chronic cluster headache states that current evidence on the efficacy of implantation of an SPG 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 SPG stimulation for chronic cluster headache.

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

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 the treatment of some conditions. However, BTX-A is not specifically approved for the treatment of cervicogenic headache or occipital neuralgia; the use of BTX-A for these diagnoses is off-label use.

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Radiofrequency Ablation

Radiofrequency ablation (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, 2026)

Electrical Stimulation

Electrical stimulation of the occipital/cranial nerves for the treatment of occipital neuralgia, cervicogenic headache, and migraines is a procedure and therefore is not subject to regulation by the FDA; however, the devices that are 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, 2026)

Nerivio Migra was granted a Class II designation through the De Novo review process as a trunk and limb electrical stimulator. While originally authorized for use in adults with acute migraine (≤ 12 headache days per month) who do not have chronic migraine, Nerivio was subsequently cleared for adults with chronic migraine in 2020 and expanded for use in adolescents with at least two migraines per month in 2021. Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K203181. (Accessed April 22, 2026)

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Policy History/Revision Information

Date	Summary of Changes
10/01/2026	**Related Policy** • Removed reference link to the Medical Policy titled *Office-Based Procedures – Site of Service* (retired Oct. 1, 2026) **Applicable Codes** • Updated list of applicable CPT codes to reflect quarterly edits; added 1057T, 1058T, 1059T, 1060T, and 1061T **Supporting Information** • Archived previous policy version 2026T0080TT

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

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

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