Headache and Occipital Neuralgia Treatments

INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS website for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
LCD LCA	Botulinum Toxins	L33646 A52848	J6, JK - National Government	IL, MN, WI

			Services, Inc. (Part A/B MAC)	CT, NY, ME, MA, NH, RI, VT
LCD LCA	Chemodenervation	**L33458** **A56646**	JJ - Palmetto GBA (Part A/B MAC)	AL, GA, TN
LCD LCA	Peripheral Nerve Blocks	**L33933** **A57788**	JN - First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, U.S. VI

Description

A number of treatments have been proposed for headaches and occipital neuralgia, including ablative techniques, injections/blocks, occipital nerve stimulation, peripherally implanted nerve stimulation or surgical procedures.

Chronic headache/occipital neuralgia can result from chronic spasm of the neck muscles as the result of either myofascial syndrome or underlying cervical spinal disease. It may be unilateral or bilateral, constant or intermittent. Nerve injury secondary to a blow to the back of the head or trauma to the nerve from a scalp laceration can also cause this condition. Most commonly it is caused by an entrapment of the occipital nerve in its course from its origin from the second cervical (C2) nerve root to its entrance into the scalp through the mid portion of the superior nuchal line.

Ablative procedures (eg, pulsed radiofrequency [RF] ablation, radiofrequency ablation [RFA], RF denervation, RF neurotomy, cryodenervation [also known as cryoablation or cryosurgery], neurolysis, rhizotomy) may be performed in an attempt to denervate the occipital nerve (greater or lesser), upper cervical nerve (eg, second cervical nerve, also known as C2), supraorbital, supratrochlear or sphenopalatine ganglion. The proposed goal of denervation is to shut off the pain signals that are sent to the brain from the nerves and/or to reduce the likelihood of, or to delay, any recurrence that may occur by selectively destroying pain fibers without causing excessive sensory loss, motor dysfunction or other complications.

Injection therapy delivers local anesthetics, steroids or other agents into the region of the affected nerve(s), thereby theoretically reducing pain and inflammation. Examples of injections/blocks used to treat headaches or occipital neuralgia include, but may not be limited to, occipital nerve block, greater occipital nerve block, C2 ganglion nerve block, sphenopalatine nerve block (with or without the use of the **SphenoCath** device), stellate ganglion block, supraorbital nerve block or supratrochlear nerve block. Sphenopalatine nerve blocks and sphenopalatine ganglion blocks, with or without the use of the SphenoCath device, have also been proposed as a treatment for trigeminal neuralgia.

During **occipital nerve stimulation (ONS)** an electrical impulse is sent to the tissue around the occipital nerves. This electrical current purports to block or disrupt the normal transmission of pain signals and creates a tingling sensation (referred to as paresthesia). ONS utilizes a set of electrodes that are implanted beneath the skin (overlying the occipital nerves) at the base of the skull, which are connected by a wire to a pacemaker-like device that is also implanted elsewhere in the body. An external generator (similar to a remote control device) controls the degree of stimulation the individual receives.

Peripherally implanted nerve stimulation, also referred to as peripheral nerve stimulation (PNS), transmits an electrical current via an electrode that has been implanted adjacent or parallel to the selected peripheral nerve.

Devices proposed for nerve stimulation for treatment or prevention of headaches include, but may not be limited to, the following:

- **Cefaly Supraorbital Transcutaneous Neurostimulator (Cefaly Enhanced)** has been proposed as an alternative to medical treatment to prevent or treat episodic migraine headache in an adult 18 years of age or older. The battery powered Cefaly is a headband-like device that sits across the forehead (just above the eyes), applying an electric current to stimulate branches of the trigeminal nerve, which is thought to be associated with migraine headaches. The device purportedly works through neuromodulatory effects on those nerves, thereby blocking pain signals. The device has both an acute mode (for treatment of a migraine as it occurs) and a prevent mode (which can be used daily to prevent future migraine attacks). The newest version of the device is the **Cefaly Connected** which is Bluetooth-enabled to be used with the **CeCe Migraine Management** app on an individual's smartphone or tablet. The **Cefaly Dual** is approved by the US Food & Drug Administration (FDA) as an over-the-counter (OTC) product (for use without a prescription) for either the prevention or treatment of migraine headache.

- The **Nerivio** device is proposed as a treatment for episodic or chronic migraine headaches with or without aura in an individual 12 years of age or older, as well as preventive therapy for migraine headache. The device is a wireless, battery-operated, noninvasive, wearable remote electrical stimulation/neuromodulation unit which is controlled by a smartphone application (it may also be referred to as a distal transcutaneous electrical nerve stimulator). It uses an armband which contains the electrodes and the power source which is applied to the upper arm (though it may be placed anywhere on the body [other than the head or neck], including the trunk or legs) to deliver the electrical nerve stimulation to peripheral nerves. This proposed treatment may also be referred to as remote electrical neuromodulation (REN).

- The **Nocira** device has recently received breakthrough device designation from the FDA for acute migraine treatment in an individual 18 years of age or older. It does not attempt to directly stimulate nerves, but instead proposes that controlled puffs of air into the external ear canal will produce subtle pressure changes that will stimulate pressure-activated sensors in the external and middle ear. Those, in turn, are theorized to stimulate multiple nerves (branches of the vagal and trigeminal nerves) that target the brain's pain centers to purportedly reset overactive pain-generating areas of the brain. The controlled puffs of air are delivered via earpieces (similar to audio earpieces) from a small pocketable-sized pump which is programmed by a smartphone app.

- Another FDA-approved device that has been proposed as a treatment option for migraine headache is the **Relivion MG** device. The Relivion MG utilizes noninvasive neuromodulation technology to concurrently stimulate the two major nerve pathways purportedly responsible for migraine symptoms by targeting and activating the six branches of the occipital and trigeminal nerves. Like the Cefaly device, it utilizes a headband that contains the electrodes and stimulator and is worn for a designated treatment period.

Surgical interventions are proposed as a treatment option to relieve impingement of the nerve root(s) and thereby eliminate symptoms caused by compression and injury to the nerves. Examples of surgical interventions include, but may not be limited to, decompression of the supratrochlear and supraorbital nerves, ganglionectomy, microdecompression of the occipital nerve, neuroplasty, occipital nerve decompression, resection/partial resection of the semispinalis capitis muscle, sensory nerve decompression, transection/avulsion of the occipital nerve or transposition of cranial sensory nerve.

Another surgical approach is vascular ligation of superficial extracranial arteries (eg, superficial branches of the external carotid artery, main trunk of the superficial temporal artery, frontal branch of the superficial temporal artery, occipital artery or posterior auricular artery) which are theorized as an origin of headache pain in some individuals.

Coverage Determination

iCare follows the CMS requirement that only allows coverage and payment for services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

The **following treatments for headache and/or occipital neuralgia** will be considered medically reasonable and necessary when the following requirements are met:

- **Botulinum toxins** (eg, Botox) **injection** when the following requirements are met[10]:
    - Chronic daily headaches (including chronic tension-type headache) characterized by the following:
        - Headache occurring more than 15 days per month; **AND**
        - Headache duration of 4 or more hours per day; **AND**
        - Headache occurring for a period of 3 or more months; **AND**
        - Individual has significant disability due to the headaches, and have been refractory to standard and usual conventional therapy;

    OR

    - Chronic migraine, characterized by the following:
        - Headache on greater than 15 days per month; **AND**

  - At least 8 headache days per month meet criteria for migraine without aura or respond to migraine-specific treatment

- For continuing Botulism toxin therapy the individual must demonstrate a significant decrease in the number and frequency of headaches and an improvement in function upon receiving Botulinum toxin.

- Under Medicare, payment is allowed for one injection per site regardless of the number of injections made into the site. A site is defined as one side of the face or neck;

- **Occipital nerve block to** confirm occipital neuralgia

- **Occipital nerve denervation** when the following requirement is met:

  - If only temporary relief of symptoms after an occipital nerve block is obtained, neurolysis of the greater, lesser or third occipital nerve may be considered via multiple techniques including radiofrequency and cryoanalgesia

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

Botulinum toxins (eg, Botox) **injection** will **not** be considered medically reasonable and necessary for the following[10]:

- Failure of 2 definitive, consecutive, treatment sessions involving a muscle or group of muscles could preclude further coverage of the serotype used in the treatment for a period of 1 year after the second session. It may be reasonable, however, to attempt treatment with a different serotype

The following **procedures or devices for the treatment of headaches or occipital neuralgia** will **not** be considered medically reasonable and necessary:

- **Injections/blocks** including, but may not be limited to:

  - C2 ganglion nerve block; **OR**
  - Supraorbital nerve block; **OR**
  - Supratrochlear nerve block; **OR**

- **Surgical interventions** including, but may not be limited to:

    - Decompression of the supraorbital and supratrochlear nerves; **OR**
    - Ganglionectomy; **OR**
    - Microdecompression of the occipital nerve; **OR**
    - Neuroplasty; **OR**
    - Occipital nerve decompression; **OR**
    - Resection/partial resection of the semispinalis capitis muscle; **OR**
    - Sensory nerve decompression; **OR**
    - Transection/avulsion of the occipital nerve; **OR**
    - Transposition of a cranial sensory nerve; **OR**

A review of the current medical literature shows that there is no evidence to determine that these services are standard medical treatments. There is an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

The following **procedures or devices for the treatment of headaches or occipital neuralgia** will **not** be considered medically reasonable and necessary:

- **Ablative techniques** including, but may not be limited to:

    - Neurolysis; **OR**
    - Pulsed radiofrequency ablation; **OR**
    - Rhizotomy; **OR**

- **Cefaly Supraorbital Transcutaneous Neurostimulator** (including the **Cefaly Connected, Cefaly Dual** and **Cefaly Enhanced**) (for neither the treatment *nor* prevention of headaches); **OR**

- Image-guided intranasal sphenopalatine ganglion block; **OR**

- **Nerivio** device (remote electrical neuromodulation [REN]; also referred to as a distal transcutaneous electrical nerve stimulator); **OR**

- **Nocira** device; **OR**

- **Occipital nerve stimulation** for *any* indication including, but may not be limited to:

    - Cervicogenic headache; **OR**
    - Cluster headache; **OR**
    - Migraine headache; **OR**
    - Neck pain; **OR**
    - Occipital neuralgia; **OR**
    - Tension headache; **OR**

- **Relivion MG** device; **OR**

- **Sphenopalatine nerve block or sphenopalatine ganglion block** (with or without use of the SphenoCath device) for any indication including, but may not be limited to, headache or trigeminal neuralgia

A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatments. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

Summary of Evidence

Cefaly Supraorbital Transcutaneous Neurostimulator
Hayes reviewed studies and found that Cefaly may be effective in the reduction of migraine days, migraine attacks, and/or use of medication for acute migraines in people with episodic migraine headaches. Evidence also consistently suggests that Cefaly is not associated with serious adverse events. One study suggested Cefaly may be a useful addition to pharmacotherapy and another study found some benefits of Cefaly over sham, but the mean benefit reported was small. Hayes states evidence comparing Cefaly with standard active treatment options are needed to better inform clinical benefit. In addition, Cefaly is available without a prescription.[21]

Image-Guided Intranasal Sphenopalatine Ganglion Block
Hayes concluded that there is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management for the use of image-guided intranasal SPG ganglion block for the treatment of migraine headaches.[34]

UpToDate states that anatomic research has shown that the SPG is not as close to the nasal mucosa as previously thought, which has raised doubt that the SPG blockade can be completed through intranasal application of local anesthetic. There is limited data that suggest benefit of SPG blocks for treatment of acute migraine.[43]

Nerivio
ECRI concluded that the evidence is somewhat favorable for Nerivio for treating migraines. Although current evidence showed consistent evidence that Nerivio reduces acute pain, migraine-associated symptoms, and medication use at 2- to 24- hour follow-up in about half or more patients aged 12 years or older experiencing episodic, chronic, and/or menstrual migraines, there are evidence gaps. Additional large confirmatory randomized controlled studies (RCTs) are needed in addition to evidence demonstrating long-term benefits.[15]

Hayes reviewed clinical studies and systematic reviews and both suggested minimal support for using Nerivio for the management of acute migraine episodes. A review of clinical practice guidelines and position statements showed weak support for use of Nerivio to manage acute migraine episodes. Two RCTs showed more effective pain management with Nerivio than a sham device and a 3 case series (without a

comparison group) reported benefits in pain management, functional improvement, and other symptoms (eg, nausea) in many patients. Although these studies showed an improvement with Nerivio, additional evidence comparing Nerivio with standard migraine care is needed to determine its clinical benefit.[22]

Occipital Nerve Stimulation

ECRI concluded that evidence was inconclusive for occipital nerve stimulation (ONS) for treating medically refractory chronic cluster headache. The evidence from 6 small case series was insufficient the efficacy of ONS or how it compares to other electrical stimulation treatments. The evidence has a high risk of bias due to small sample size and lack of controls, randomization, and blinding.[17]

Hayes determined that the available studies did not provide sufficient evidence to evaluate ONS for chronic cluster headache. There was very low-quality evidence that ONS may have some benefits to patients with refractory symptoms due to chronic cluster headache however no conclusions could be made due to the lack of controlled studies of ONS for cluster headache and the small size of uncontrolled studies.[25] Hayes concluded that ONS appears to have a positive but variable treatment effect on headache outcomes in selected patients. This conclusion was based on low-quality body of evidence.[26]

UpToDate states there is no proven effective treatment for cervicogenic headache. There is a 3 year retrospective study that evaluated ONS for 16 patients with refractory cervicogenic headache. Although 11 patients reported 50% or more improvement in headache pain scores at 1 year post-implant and similar level of improvement was noted in 6 patients at 3 years post-implant, further validation of this technique is necessary in cervicogenic headache.[44]

UpToDate reports there are inconsistent data from small, randomized trials regarding the benefit of ONS for the treatment of chronic migraine.[45]

UpToDate lists ONS as a promising but unproven method using neurostimulation to treat medically refractory cluster headache. ONS is investigational and requires further study to confirm long-term benefit and safety. There are small observational studies that reported benefits for some patients with cluster headache. In a study of 131 patients with medically refractory chronic cluster headache, ONS was associated with an improvement in frequency and severity of cluster attacks. At 24 weeks, 45 percent of patients reported at least a 50 percent reduction in attack frequency. However, complications including infection and lead migration may limit the effectiveness of this therapy. There were also adverse events including localized pain, neck stiffness, lead migration, and electrode damage. Additional data are needed to help guide patient selection, to optimize the stimulation protocol, and to establish long-term safety of device implantation.[46]

UpToDate states ONS has been used in certain cases of severe occipital neuralgia unresponsive to other less invasive treatments. ONS should be reserved for use in pain centers with neuromodulation expertise.[47]

Congress of Neurological Surgeons (CNS) gave a Level III recommendation for ONS as a treatment option for patients with medically refractory occipital neuralgia. This recommendation is the lowest level recommendation from CNS and is defined as evidence from case series, comparative studies with historical controls, case reports, and expert opinion, and significantly flawed randomized, controlled trials. According to the CNS, ONS is a promising therapy for medically refractory occipital neuralgia, but an adverse effect is lead migration.[13]

Sphenopalatine Nerve Block or Sphenopalatine Ganglion Block
Hayes noted that three studies suggest sphenopalatine ganglion (SPG) block using an anesthetic decreases the pain of migraine although there is a lack of clinical evidence demonstrating the benefits are clinically important compared with sham or active treatments.[23]

UpToDate lists SPG stimulation as a promising but unproven method of neurostimulation to treat medically refractory cluster headaches. Future studies are needed to confirm long-term benefit and safety.[46]

The US Department of Veterans Affairs (VA/DoD) does not have a recommendation for or against the use of SPG block for the treatment of headache due to insufficient evidence.[52]

The American Headache Society added SPG stimulation to their guideline with a Level B recommendation for acute treatment of cluster headaches. The Level B recommendation is defined as probably effective, ineffective, or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population.[5]

Surgical Interventions
Occipital nerve decompression
UpToDate reports that occipital nerve decompression may benefit selected patients however it is not a routine therapeutic treatment and should be reserved for use in tertiary care centers with expertise in peripheral nerve neurosurgery. A small series of 11 patients with medically refractory occipital neuralgia had decompression at the level of the semispinalis capitis and trapezial tunnel. Three patients had pain resolution, 6 reported significant pain relief, and 2 patients reported no pain improvement over a mean follow-up period of 12 months. In another series of patients with occipital neuralgia, 6 out of 11 patients had pain resolution at 6 months post-surgical decompression and 1 patient failed to get relief.[47]

Vascular ligation of superficial extracranial arteries
According to Hayes, there is minimal published literature documenting outcomes of vascular ligation, cauterization, or resection for the treatment of migraine headaches. Hayes reports there is insufficient evidence to assess the safety and/or impact on health outcomes or patient management of vascular ligation for the treatment of migraine headaches.[35]

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
20999	Unlisted procedure, musculoskeletal system, general	
37799	Unlisted procedure, vascular surgery	

64400	Injection(s), anesthetic agent(s) and/or steroid; trigeminal nerve, each branch (ie, ophthalmic, maxillary, mandibular)	
64405	Injection(s), anesthetic agent(s) and/or steroid; greater occipital nerve	
64450	Injection(s), anesthetic agent(s) and/or steroid; other peripheral nerve or branch	
64505	Injection, anesthetic agent; sphenopalatine ganglion	
64510	Injection, anesthetic agent; stellate ganglion (cervical sympathetic)	
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)	
64575	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)	
64585	Revision or removal of peripheral neurostimulator electrode array	
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling	
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver	
64600	Destruction by neurolytic agent, trigeminal nerve; supraorbital, infraorbital, mental, or inferior alveolar branch	
64640	Destruction by neurolytic agent; other peripheral nerve or branch	
64722	Decompression; unspecified nerve(s) (specify)	
64744	Transection or avulsion of; greater occipital nerve	
64999	Unlisted procedure, nervous system	
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming	

95971	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	
95972	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
C1767	Generator, neurostimulator (implantable), nonrechargeable	
C1778	Lead, neurostimulator (implantable)	
C1787	Patient programmer, neurostimulator	
C1816	Receiver and/or transmitter, neurostimulator (implantable)	
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system	
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system	
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller	
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)	
C1897	Lead, neurostimulator test kit (implantable)	
E1399	Durable medical equipment, miscellaneous	

K1023	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm	
L8680	Implantable neurostimulator electrode, each	**Not Covered**
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only	
L8682	Implantable neurostimulator radiofrequency receiver	
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver	
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension	**Not Covered**
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension	**Not Covered**
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension	**Not Covered**
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension	**Not Covered**
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only	
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only	

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Change Summary

- 01/01/2024 New Policy.