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# MEDICAL POLICY – 7.01.563 Ablative Treatments for Occipital Neuralgia, Chronic Headaches, and Atypical Facial Pain

Effective Date:	Oct. 1, 2024	RELATED I	MEDICAL POLICIES:
Last Revised:	Sept. 23, 2024	7.01.125	Occipital Nerve Stimulation
Replaces:	N/A	7.01.159	Sphenopalatine Ganglion Block for Headache
		7.01.555	Facet Joint Denervation
		7.01.564	Pulsed Radiofrequency
		7.01.565	Ablation of Peripheral Nerves to Treat Pain

### Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION EVIDENCE REVIEW | REFERENCES | HISTORY

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### Introduction

Nerves send messages to the brain, including pain signals. When there's an injury or other problem, a message of pain travels along the nerve, to the spinal cord, and then into the brain. One way to try to treat chronic pain is to destroy—ablate—a small portion of the nerve that's sending the pain signal. This technique has been well studied and is proven in very limited situations. However, destroying part of a nerve to try to treat chronic headaches or facial pain is investigational (unproven). While some small, early studies have shown promise, more, larger, and longer high-quality studies are needed to determine whether nerve ablation is truly effective for chronic headaches and facial pain.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

#### **Policy Coverage Criteria**

Pr	ocedure	Investigational		
Ablative procedures for		Ablative procedures for the treatment of chronic headaches		
the treatment of:		(chronic migraines, chronic tension-type headaches, chronic		
•	Chronic migraines	cluster headaches, cervicogenic headaches), occipital neuralgia,		
•	Chronic tension-type	and persistent idiopathic facial pain (PIFP)/atypical facial pain are		
	headaches	considered investigational.		
٠	Cluster headaches			
٠	Cervicogenic	Ablative procedures include, but are not limited to the following:		
	headaches	Chemical neurolysis (chemodenervation)		
• 0	Occipital neuralgia	Called and information and lating		
٠	Persistent idiopathic	Cooled radiotrequency ablation		
	facial pain (PIFP)	Cryoneurolysis (cryoablation)		
		Pulsed radiofrequency		
		Radiofrequency ablation (RFA)		

# Coding

Code	Description
СРТ	
62281	Injection/infusion of neurolytic substance (e.g., alcohol, phenol, iced saline solutions), with or without other therapeutic substance; epidural, cervical or thoracic
64600	Destruction by neurolytic agent, trigeminal nerve; supraorbital, infraorbital, mental, or inferior alveolar branch
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)
64640	Destruction by neurolytic agent; other peripheral nerve or branch
64999	Unlisted procedure, nervous system (used to report RFA)

**Note**: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).



**Related Information** 

N/A

### **Evidence Review**

### Description

Several procedures or treatments have been proposed for the treatment of chronic headaches (chronic migraines, chronic tension-type headaches, chronic cluster headaches, and cervicogenic headaches), occipital neuralgia, and persistent idiopathic facial pain (PIFP) when conventional treatments such as oral and injectable pharmacological treatments, physical therapy, chiropractic care, or transcutaneous nerve stimulation (TENS) have failed. These procedures include chemical neurolysis, cryoablation, pulsed radiofrequency, and radiofrequency ablation. The proposed effect of these procedures is to inhibit the transmission of pain signals that are sent to the brain from the sensory nerves such as the occipital nerve (greater or lesser), upper cervical nerves, supraorbital and supratrochlear nerves (branches of the frontal and trigeminal nerves), or sphenopalatine ganglion nerve.

### Background

### Headaches

The International Headache Society (IHS) created a headache classification system (the International Classification of Headache Disorders, 3<sup>rd</sup> edition) which is considered the standard for diagnosis of all types of headaches. The third edition was published in January of 2018, thirty years after its first publication in 1988. The three classifications are: primary headaches, secondary headaches and painful cranial neuropathies, and other facial pains and other

headaches. See the description for these chronic headache types along with diagnostic criteria below in **Practice Guidelines and Position Statements.** 

#### **Chronic Migraine**

Chronic migraine is believed to affect 2 percent of the world population. It is defined by having 15 or more headache days a month lasting at least 4 hours per day for more than 3 months. Chronic migraines occur more often in women and may be accompanied by sensitivity to light or sound along with nausea and/or vomiting.

#### **Chronic Tension-Type Headache**

Chronic tension-type headaches are episodic occurring on 15 or more days a month for over 3 months, lasting hours or days, and may be unremitting. They usually occur on both sides of the head and are described as a pressing or tightening feeling around the head.

#### **Chronic Cluster Headache**

Chronic cluster headaches are rare and classified as one of the trigeminal autonomic cephalalgias (TACs). They usually occur on one side of the head around one eye or temple, have a sudden onset, and are generally severe and intense, lasting for minutes or several hours at a time, over a year or longer without remission. These headaches occur more frequently in men. The cause is unknown. Common descriptors used to describe the headaches are "excruciating," "feeling like an ice pick is being driven through my eye," or "explosive." Common symptoms that accompany the headaches: coming on just as a person goes to sleep, tearing in the affected eye, drooping eyelid of the affected eye, and experiencing nasal stuffiness or a runny nose.

#### **Cervicogenic Headache**

Cervicogenic headache is considered a secondary headache where headache pain is referred from bony structures or soft tissues of the neck. Involvement of the C2-3 zygapophyseal joint is the most frequent source of cervicogenic headache in up to 70 percent of cases. Cervical range of motion may be reduced and the headache may be made worse with certain movements of the neck or when pressure is applied to certain spots in the neck. The diagnosis may be confirmed with two anesthetic blocks of the suspected pain generator, performed at different times, and associated with pain relief that is in keeping with the anesthetic used.

# Occipital Neuralgia

Occipital neuralgia is a rare type of headache described as short bursts of stabbing, throbbing, or shooting pain in the upper neck which spreads to the back of the head and is transmitted by the occipital nerves, usually to only one side of the head. It commonly develops spontaneously, with a sudden onset, and may also be accompanied by decreased or abnormal sensation in the affected area. There are generally no neurologic deficits found on exam, but there may be tenderness over the affected nerve branches when palpated. The exact pathophysiology is unknown. One theory is that it may arise from injury to the C2-C3 nerve roots and/or occipital nerves via entrapment, trauma (such as whiplash), or inflammation.

Diagnosis is generally confirmed when pain relief is obtained by a local anesthetic block to the occipital nerves.

# Persistent Idiopathic Facial Pain (PIFP)

Persistent idiopathic facial pain (PFIP), previously known as atypical facial pain, is characterized by persistent facial and/or oral pain recurring daily for 2 hours or more per day for greater than 3 months. There is no associated clinical neurological deficit. Most cases are seen in women. The pain is commonly felt around the mouth or chin but is generally poorly localized and does not follow the distribution of a peripheral nerve. The pain is possibly thought to be related to injury to the face, teeth, or gums. It is described as dull, aching, or of a nagging quality. It is generally a diagnosis of exclusion.

### **Ablative Treatments**

#### **Chemical Neurolysis (Chemodenervation)**

Chemical neurolysis, also known as chemical ablation, chemodenervation, or chemical denervation, is the application of a chemical destructive agent (e.g., phenol, ethyl alcohol, glycerol, or hypertonic saline) to a nerve to create a long-lasting or permanent interruption of neural transmission. It is usually used to relieve pain.

#### **Cooled Radiofrequency Ablation**

Cooled radiofrequency is a minimally invasive method in which a radiofrequency generator transmits a small current of thermal radiofrequency energy through an insulated, water-cooled, electrode or probe placed within tissue to target the sensory nerves responsible for sending pain signals. Coolief (Haylard Health) circulates water through the device while heating nervous tissue to create a larger treatment area than conventional radiofrequency is able to treat. "This combination of ionic heating, produced by the friction of charged water molecules, and cooling deactivates the nerves responsible for sending pain signals to the brain by targeting the pain-transmitting nerves without excessive heating, leading to pain relief."<sup>27</sup> Coolief is performed in an outpatient setting.

### Cryoneurolysis (Cryoablation)

Cryoneurolysis, also known as cryodenervation, cryoablation, cryotherapy, or cryoanalgesia, temporarily blocks nerve conduction along peripheral pathways using a small probe to freeze the target nerve and treat a variety of painful conditions. Cryoneurolysis treatments that use nitrous oxide (boiling point of -88.5  $^{\circ}$  C) as the coolant are reversible. Nerves treated in this temperature range experience a disruption of the axon, with Wallerian degeneration occurring distal to the site of injury. The axon and myelin sheath are affected, but the connective tissues remain intact. The axon can regenerate along the nerve path, usually at the rate of 1-2 mm per day. Thus, the nerve basically dies as it freezes, which stops the pain signals from transmitting. However, over time the nerve regrows, which may mean recurrence of the pain. Cryoneurolysis differs from cryoablation in that cryoablation treatments use liquid nitrogen (boiling point of -195.8° C) as the coolant. Treatments of the nerve in this temperature range are irreversible as

the nerves experience a disruption of both the axon and the endoneurium connective tissue layer.

#### **Pulsed Radiofrequency**

Pulsed radiofrequency (PRF) is a non-or minimally neurodestructive technique, where short bursts of radiofrequency energy are applied to nervous tissue to treat various chronic pain syndromes. It is seen as an alternative to continuous (non-pulsed) radiofrequency ablation, as it is theorized to have significantly less complications or side effects. Its exact mechanism of action is unclear.

Pulsed radiofrequency is delivered in short bursts, twice per second, followed by a quiet phase in which no current is applied. This allows for cooling of the electrode keeping it below the neurodestructive threshold of 45° C. Pulsing the radiofrequency current allows the power output of the generator to be greatly increased, allowing for far stronger electrical fields than in continuous radiofrequency. For example, the voltage output is usually 15-25 volts for the continuous mode radiofrequency. The pulsed radiofrequency output is 45 volts. As a result, higher voltages can be applied in pulsed radiofrequency. Because the average temperature near the pulsed radiofrequency electrode does not reach the neurodestructive range, the risk of destroying nearby tissue is reduced.

#### **Radiofrequency Ablation (RFA)**

Radiofrequency ablation (RFA) is a minimally invasive method that involves the use of heat and coagulation necrosis to destroy nerve tissue. A needle electrode is inserted through the skin and into the tissue around the nerve to be ablated. A high-frequency electrical current is applied to the target tissue which heats the nerve, causing coagulation necrosis and destruction of the nerve. It is theorized that the thermal lesioning of the nerve destroys peripheral sensory nerve endings, resulting in the alleviation of pain.

# Summary of Evidence

For individuals who have various types of headaches (chronic migraines, chronic tension-type headaches, chronic cluster headaches, and cervicogenic headaches as well as occipital neuralgia and persistent idiopathic facial pain) who received ablative treatments such as chemical neurolysis, cryoablation, pulsed radiofrequency, and RFA, the evidence includes randomized controlled trials, prospective studies, retrospective studies, and case reports. Some studies yielded promising results showing improvement in pain and decrease in pain medication usage. However, despite these encouraging clinical studies, conclusive evidence demonstrated in well-designed clinical studies in support of chemical neurolysis, cryoablation, pulsed radiofrequency, or radiofrequency ablation in the treatment of headaches and atypical facial pain is warranted.

While these treatment modalities appear to be safe, the evidence of efficacy is limited. Further placebo-controlled trials are needed. The overall quality of evidence is low. All studies were limited by methodological flaws, such as small sample size, lack of a control group, and short follow-up. Before definitive conclusions can be drawn, there is a need for high-quality studies with larger populations, adequate follow-up time, standardized treatment protocols, and comparisons of the treatment being studied with other treatments used for the same diagnosis which have also failed conventional treatments. The evidence is insufficient to determine the effects of this technology on net health outcomes.

# **Ongoing and Unpublished Clinical Trials**

There are currently no ongoing trials that might influence this review.

# **Practice Guidelines and Position Statements**

# International Headache Society (IHS)

In 2018, the International Headache Society issued the International Classification of Headache Disorders 3<sup>rd</sup> edition (ICHD-3) which states:

#### **Chronic Migraine**

- Is a common disabling primary headache disorder with two major types: migraine without aura and migraine with aura
- Headaches (migraine-like or tension-type-like) on  $\geq$  15 days/month for > 3 months, and
  - Occurs in a patient who has had at least 5 attacks on ≥ 8 days/month for > 3 months fulfilling the following criteria:
    - Migraine without aura: recurrent headache disorder manifesting in attacks lasting 4-72 hours (when untreated or unsuccessfully treated)
      - Typical characteristics of the headache: unilateral location, pulsating quality, moderate or severe intensity, aggravation by routine physical activity, and association with nausea and/or photophobia and phonophobia
    - Migraine with aura: recurrent attacks, lasting minutes, of unilateral fully reversible visual, sensory or other central nervous system symptoms that usually develop gradually and are usually followed by a headache and associated migraine symptoms
    - At least two attacks fulfilling the following criteria:
      - One or more of the following fully reversible aura symptoms: visual, sensory, speech and/or language, motor, brainstem, retinal
      - At least three of the following six characteristics: at least one aura symptom spreads gradually over ≥ 5 minutes, two or more aura symptoms occur in succession, each individual aura symptom last 5-60 minutes, at least one aura symptom is unilateral, at least one aura symptom is positive, the aura is accompanied, or followed within 60 minutes, by headache

#### Chronic Tension-Type Headache (TTH)

- A disorder evolving from frequent episodic tension-type headache, with daily or very frequent episodes of headache
- Considered a primary headache disorder

- Headache occurring on  $\geq$  15 days/month on average for > 3 months ( $\geq$ 180 days/year), fulfilling the following criteria:
  - Lasting hours to days, or unremitting
    - At least two of the following characteristics: bilateral location, pressing or tightening (non-pulsating) quality, mild or moderate intensity, not aggravated by routine physical activity
    - Neither moderate or severe nausea nor vomiting
    - No more than one of photophobia or phonophobia

#### Chronic Cluster Headache

- Is one of the trigeminal autonomic cephalalgias (TACs)
- Is considered a primary headache disorder, but may be secondary to another disorder
- The TACs share the clinical features of unilateral headache, and usually prominent cranial parasympathetic autonomic features, which are lateralized and ipsilateral to the headache
  - Cluster headache attacks occurring for one year or longer without remission, or with remission periods lasting less than 3 months.
  - At least five attacks fulfilling severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15-180 minutes (when untreated)
  - Either or both of the following:
    - At least one of the following symptoms or signs, ipsilateral to the headache:
      - Conjunctival inflammation (redness) and/or lacrimation
      - Nasal congestion and/or rhinorrhea
      - Eyelid edema
      - Forehead and facial sweating
      - Miosis and/or ptosis

• A sense of restlessness or agitation

#### Cervicogenic Headache

- Secondary headache causally associated with cervical myofascial pain sources (myofascial trigger points)
- Headache caused by a disorder of the cervical spine and its component bony, disc, and/or soft tissue elements, usually but not invariably accompanied by neck pain
  - Clinical and/or imaging evidence of a disorder or lesion within the cervical spine or soft tissues of the neck, known to be able to cause headache
  - Evidence of causation demonstrated by at least two of the following:
    - Headache has developed in temporal relation to the onset of the cervical disorder or appearance of the lesion
    - Headache has significantly improved or resolved in parallel with improvement in or resolution of the cervical disorder or lesion
    - Cervical range of motion is reduced, and headache is made significantly worse by provocative maneuvers
    - Headache is abolished following diagnostic blockade of a cervical structure or its nerve supply

#### **Occipital Neuralgia**

- Unilateral or bilateral paroxysmal, shooting or stabbing pain in the posterior part of the scalp, in the distribution(s) of the greater, lesser and/or third occipital nerves, sometimes accompanied by diminished sensation or dysesthesia in the affected area and commonly associated with tenderness over the involved nerve(s)
- Classified as painful lesions of the cranial nerves and other facial pain

- Unilateral or bilateral pain in the distribution(s) of the greater, lesser and/or third occipital nerves and fulfilling the following criteria:
  - Recurring in paroxysmal attacks lasting from a few seconds to minutes
  - Severe in intensity
  - Shooting, stabbing, or sharp in quality
- Pain is associated with both of the following:
  - Dysesthesia and/or allodynia apparent during innocuous stimulation of the scalp and/or hair
  - Either or both of the following
    - Tenderness over the affected nerve branches
    - Trigger points at the emergence of the greater occipital nerve or in the distribution of C2
- Pain is eased temporarily by local anesthetic block of the affected nerve(s)

#### Persistent Idiopathic Facial Pain (PIFP)

- Previously known as atypical facial pain
- Persistent facial and/or oral pain, with varying presentations but recurring daily for more than two hours/day over more than 3 months, in the absence of clinical neurological deficit
- Classified as painful lesions of the cranial nerves and other facial pain
  - Facial and/or oral pain fulfilling the following criteria:
    - Recurring daily for > 2 hours/day for > 3 months
    - Pain has both of the following characteristics:
      - Poorly localized, and not following the distribution of a peripheral nerve
      - Dull, aching, or nagging quality



- Clinical neurological examination is normal
- A dental cause has been excluded by appropriate investigations

# American Society of Anesthesiologists and American Society of Regional Anesthesia and Pain Medicine

In 2010, the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine issued practice guidelines for Chronic Pain Management which included the following:

Ablative techniques include chemical denervation, cryoneurolysis or cryoablation, thermal intradiscal procedures (i.e., intervertebral disc annuloplasty [IDET], transdiscal biaculoplasty), and radiofrequency ablation.

- Chemical denervation: (e.g., alcohol, phenol, or high-concentration local anesthetics) should not be used for routine care of patients with chronic noncancer pain
- Cryoneurolysis or cryoablation: may be used in the care of selected patients (e.g., postthoracotomy pain syndrome, low back pain [medial branch], and peripheral nerve pain)
- Radiofrequency ablation: conventional radiofrequency ablation may be performed for neck pain, and water-cooled radiofrequency ablation may be used for chronic sacroiliac joint pain. Conventional or thermal radiofrequency ablation of the dorsal root ganglion should not be routinely used for the treatment of lumbar radicular pain

# Medicare National Coverage

There is no national coverage determination.

# **Regulatory Status**

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) premarket approval process. Two product codes are dedicated to these devices, one for radiofrequency lesion generators (GXD) and one for radiofrequency lesion probes (GXI) (FDA, 2016)

In 2017 the US Food and Drug Administration (FDA) cleared for marketing (K163461) COOLIEF (Halyard Health, Inc.) radiofrequency lesion probe. It is to be used in conjunction with a radiofrequency generator to create lesions in nervous tissue. Cooled radiofrequency (Cooled RF) is also indicated for creating radiofrequency lesions of the genicular nerves for the management of moderate to severe knee pain of more than 6 months in individuals with radiologically confirmed osteoarthritis and a positive response to a diagnostic genicular nerve block.

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#### History

Date	Comments	
09/01/18	New policy, approved August 14, 2018, effective December 6, 2018. Add to Surgery section. Policy created with a literature review through July 2018. Ablative procedures, including but not limited to chemical neurolysis, cryoablation, pulsed radiofrequency, and radiofrequency ablation for the treatment of chronic headaches (chronic migraines, chronic tension-type headaches, chronic cluster headaches, cervicogenic headaches), occipital neuralgia and persistent idiopathic facial pain (PIFP)/atypical facial pain are considered investigational.	
10/01/19	Annual Review, approved September 5, 2019. Policy updated with literature review through August 2019. References added. Cooled radiofrequency added to list of ablative treatments considered investigational.	

Date	Comments
08/01/20	Updated Related Policies. 7.01.565 is now 7.01.154.
10/01/20	Annual Review, approved September 1, 2020. Policy reviewed. Policy statement unchanged.
06/01/21	Annual Review, approved May 4, 2021. Policy reviewed. References updated. Policy statements unchanged.
09/01/22	Annual Review, approved August 8, 2022. Policy updated with literature review through July 18, 2022. References added and updated. Policy statements unchanged.
09/01/23	Annual Review, approved August 21, 2023. Policy updated with literature review through July 17, 2023. References added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
03/01/24	Updated Related Policies. 7.01.154 is now 7.01.565.
10/01/24	Annual Review, approved September 23, 2024. Policy updated with literature review through August 26, 2024. Reference added. Policy statements unchanged. Added CPT code 64999 to report RFA.

**Disclaimer**: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2024 Premera All Rights Reserved.

**Scope**: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.