Clinical Policy Title: Invasive treatment for cervicogenic headache and occipital neuralgia

Clinical Policy Number: 09.02.02

Effective Date: June 1, 2014
Initial Review Date: February 19, 2014
Most Recent Review Date: February 6, 2018
Next Review Date: February 2019

Related policies:

CP# 00.02.02 Botulinum toxin products
CP# 03.02.02 Radiofrequency ablation treatment for spine pain
CP# 03.02.03 Acupuncture
CP# 03.03.05 Spine pain — trigger point injections
CP# 03.03.06 Biofeedback for chronic pain
CP# 09.02.05 Sphenopalatine ganglion block injections for headache
CP# 09.02.08 Cryoneurolysis
CP# 10.02.06 Ambulatory continuous peripheral nerve block for chronic pain

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Coverage policy

AmeriHealth Caritas considers the following interventions for treatment of cervicogenic headache or occipital neuralgia to be investigational and, therefore, not medically necessary:

- Injection of local anesthetics and/or steroids, used as occipital nerve blocks (Hayes, 2017; Blumenfeld, 2013; Hayes, 2011). See also Clinical Policy 03.02.01 Spine pain (non-surgical) for the use of facet/zygapophysial joint or medial branch nerve block injections.
• Botulinum toxin Type A (Hayes, 2017; Peloso, 2013; American College of Occupational and Environmental Medicine [ACOEM], 2011). See also Clinical Policy 00.02.02 Botulinum toxin products.
• Ablative treatments (Falco, 2012; ACOEM, 2011; Hayes, 2011). See also Clinical Policy 03.02.02 Radiofrequency ablation treatment for spine pain and Clinical Policy 09.02.08 Cryoneurolysis.
• Neurosurgical treatments (Hayes, 2011).

For Medicare members only:

AmeriHealth Caritas considers the use of percutaneous insertion of a peripheral nerve stimulation electrode, in the direct vicinity of the stimulated nerve (e.g., occipital nerve), for the treatment of cervicogenic headache or occipital neuralgia to be clinically proven and, therefore, medically necessary when all of the following criteria are met (L34328 Peripheral Nerve and Peripheral Nerve Field Stimulation):
• Documented chronic and severe pain for at least three months.
• Documented failure of less invasive treatment modalities and medications.
• Lack of surgical contraindications, including infections and medical risks.
• Appropriate proper patient education, discussion, and disclosure of risks and benefits.
• No active substance abuse issues.
• Formal psychological screening by a mental health professional.
• Successful stimulation trial with $\geq 50$ percent reduction in pain intensity, before permanent implantation.

AmeriHealth Caritas considers the use of cryoneurolysis to be clinically proven and, therefore, medically necessary for treatment of occipital neuralgia, when only temporary relief of symptoms is obtained from an occipital nerve block. Neurolysis of the greater occipital nerve may be considered via multiple techniques, including radiofrequency and cryoanalgesia (L33933 Peripheral Nerve Blocks).

AmeriHealth Caritas considers all other types of peripheral nerve stimulation for the treatment of cervicogenic headache or occipital neuralgia to be investigational and, therefore, not medically necessary.

Limitations:

For certain other clinical uses, the above treatments may be considered clinically proven as the effectiveness of these uses has been established in peer-reviewed professional literature. These clinically proven uses are identified in the following policies:
This policy excludes diagnoses of primary headache types, including but not limited to migraine with or without aura and chronic tension-type headaches (See pages 3 – 4 of this policy for diagnostic criteria.).

**Alternative covered services:**

- Pain management program.
- Physical therapy or occupational therapy.
- Prescription drug therapy as appropriate.
- Physician consultation.

**Background**

Neck pain and tenderness are common symptoms of many headache disorders. Cervicogenic headache and occipital neuralgia are specific headache types, believed to be caused by pathology of the cervical vertebrae or the occipital nerves. Diagnosis requires differentiating these headache disorders from other types, including more common primary headache disorders, such as migraine with or without aura and chronic tension-type headache. Occipital neuralgia must be distinguished from occipital referral of pain from the atlantoaxial or upper zygapophyseal joints, or from tender trigger points in neck muscles or their insertions (International Headache Society [IHS], 2014).

Diagnosis may involve the use of clinical criteria, diagnostic imaging, and fluoroscopically guided, controlled, diagnostic nerve blocks. The IHS (2014) lists diagnostic criteria to assist in the differential diagnosis (Tables 1 and 2). The Cervicogenic Headache International Study Group (CHISG) also lists diagnostic criteria for cervicogenic headache, with notable variations between the two organizations (Sjaastad, 2000). For example, the CHISG criteria for cervicogenic headache include unilateral head pain, while the IHS criteria note referred pain from a source in the neck, not constrained by unilaterality. Such inconsistencies highlight the difficulty in differentiating various types of headaches and estimating their prevalence in the general population using available criteria.

**Table 1: IHS diagnostic criteria for cervicogenic headache and occipital neuralgia**

<table>
<thead>
<tr>
<th>Cervicogenic headache</th>
<th>Occipital neuralgia</th>
</tr>
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<tbody>
<tr>
<td>Pain referred from a source in the neck and perceived in one or more regions of the head and/or face.</td>
<td>Paroxysmal, stabbing pain, with or without persistent aching between paroxysms, in the distribution of the greater, lesser, and/or third occipital nerves.</td>
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<tr>
<td>Clinical, laboratory, and/or imaging evidence of a disorder or lesion within the cervical spine or soft tissues of the neck, known to be or generally accepted as a valid cause of headache.</td>
<td>Tenderness over the affected nerve.</td>
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</tbody>
</table>
Evidence that the pain can be attributed to the neck disorder or lesion, based on either demonstration of clinical signs that implicate a source of pain in the neck, or abolition of headache following diagnostic blockade of a cervical structure, or its nerve supply using placebo or other adequate controls.

Pain resolves within three months after successful treatment of the causative disorder or lesion.

Table 2: IHS diagnostic criteria for common primary headache disorders

<table>
<thead>
<tr>
<th>Cervicogenic headache</th>
<th>Occipital neuralgia</th>
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<tbody>
<tr>
<td>Evidence that the pain can be attributed to the neck disorder or lesion, based on either demonstration of clinical signs that implicate a source of pain in the neck, or abolition of headache following diagnostic blockade of a cervical structure, or its nerve supply using placebo or other adequate controls.</td>
<td>Pain eased temporarily by local anesthetic block of the nerve.</td>
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<tr>
<td>Pain resolves within three months after successful treatment of the causative disorder or lesion.</td>
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</table>

Numerous treatment options for cervicogenic headache and occipital neuralgia have been proposed. Conservative treatment options include pharmacotherapy with oral analgesics, anti-inflammatory medications, tricyclic antidepressants, and anticonvulsant medications, used alone or in combination with other treatment modalities. Other noninvasive interventions may involve a cervical collar during the acute phase, physical therapy, postural training, relaxation exercises, transcutaneous electrical...
nerve stimulation, and spinal manipulation.

More invasive treatments include local injection therapy, ablation, neurosurgery, and peripheral nerve stimulation. Evidence-based guidelines generally recommend conservative options as the first-line treatment for cervicogenic headache and occipital neuralgia, reserving more invasive options for those with chronic, severe pain that does not respond to conservative treatment (American Association of Neurological Surgeons [AANS], 2013).

Local injection therapy delivers local anesthetics, steroids, or other agents into the region of the affected nerve(s), thereby reducing pain and inflammation. Botulinum Toxin Type A is a neurotoxin that blocks nerve impulses and has been proposed as treatment for cervicogenic headache and occipital neuralgia. The U.S. Food and Drug Administration (FDA) approved Botulinum Toxin Type A (onabotulinumtoxinA, marketed as Botox®, Allergan Inc.) for the treatment of severe dystonia, severe primary axillary hyperhidrosis, strabismus, blepharospasm neurogenic detrusor over activity, chronic migraine, and upper limb spasticity; therefore, treatment for cervicogenic headache or occipital neuralgia is an off-label use (FDA, 2014).

Neuroablative techniques are used to selectively and temporarily interrupt aberrant signal pathways to relieve chronic pain. For treatment of occipital neuralgia and cervicogenic headache, ablation may be performed in an attempt to denervate the greater or lesser occipital nerve; upper cervical nerve (e.g., second cervical nerve); or the supraorbital, supratrochlear, or sphenopalatine ganglion. There are numerous FDA-approved devices used in performing radiofrequency ablation, but none has been approved to treat cervicogenic headache or occipital neuralgia. Ablative techniques include, but are not limited to:

- Pulsed radiofrequency ablation.
- Non-pulsed radiofrequency ablation.
- Radiofrequency neurotomy.
- Radiofrequency denervation.
- Neurolysis.
- Cryodenervation.
- Nerve root rhizotomy.

Neurosurgery is performed to relieve impingement of the nerve root(s) and thereby eliminate symptoms caused by compression and injury to the cervical nerves. A number of surgical procedures have been studied for the treatment of occipital neuralgia and cervicogenic headache, including:

- Dorsal nerve root section.
- Occipital neurectomy.
- Partial posterior rhizotomy.
- Cervical spine disc excision with fusion.
- Surgical nerve release.
Peripheral nerve stimulation entails the placement of electrodes near or on a selected peripheral nerve, as a form of neuromodulation therapy. Peripheral nerve stimulation is delivered transcutaneously, percutaneously, and by using an implantable device. Occipital nerve stimulation (also called peripheral nerve stimulation of the occipital nerve) delivers a small electrical charge to the occipital nerve in an attempt to prevent migraines and other headaches in patients who have not responded to medications. Several devices are approved for electrically stimulating peripheral nerves to relieve severe intractable pain, but currently no implantable pulse generator, radiofrequency device, or leads are FDA approved for peripheral occipital nerve stimulation to treat occipital neuralgia or cervicogenic headache.

Searches

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on December 26, 2017. Search terms were: “post-traumatic headache” (MeSH), “cervicogenic headache,” “chronic neck pain,” and “occipital neuralgia,” limited to human studies published in English.

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

Six systematic reviews and no economic analyses were identified for this policy. The available evidence is insufficient to conclude that local injection therapy, ablation, surgery, or peripheral nerve stimulation are effective treatments for occipital neuralgia or cervicogenic headache. The limited data suggest that some patients may obtain a short-term benefit from some of these treatment methods, but a substantial proportion of patients experienced recurrences.

Studies included patients with pain refractory to conventional treatment and frequently uncertain
etiologies based on criteria from diagnostic nerve blockades, which have not been standardized or sufficiently validated in the context of occipital neuralgia or cervicogenic headache. Where reported, types of interventions and follow-up periods varied, subjective rather than objective outcome measures were used, and the long-term efficacy and safety remain unknown. Few randomized controlled trials (RCTs) were available, and most recommendations from professional societies rely on the results of significantly flawed observational studies.

**Local injection therapy:**

Three systematic reviews found moderately strong evidence from RCTs of no benefit of anesthetic nerve block for treatment of cervicogenic headache (Peloso, 2013; Gross, 2013; Falco, 2012). One systematic review found fair evidence of short-term benefit from one small RCT (Hayes, 2011). The AHS Special Interest Section for Peripheral Nerve Blocks and Other Interventional Procedures also cited the paucity of evidence for treatment of most headache disorders and cranial neuralgias, excluding cluster headaches (Blumenfeld, 2013).

The AANS (2013) states: “Percutaneous nerve blocks not only may be helpful in diagnosing occipital neuralgia, but they can help alleviate pain, as well. Nerve blocks involve either the occipital nerves or, in some patients, the C2 and/or C3 ganglion nerves. It is important to keep in mind that the use of steroids in nerve block treatment may cause serious adverse effects.” The ASA/ASRA (2010) strongly recommend using medial branch blocks for facet-mediated spine pain, but are against using peripheral somatic nerve blocks for long-term treatment of chronic pain, based on observational studies suggesting short-term relief.

**Botulinum Toxin Type A:**

Two recent systematic reviews found strong evidence of no benefit (versus control) or no difference (versus another treatment) for its use as treatment for cervicogenic headache (Peloso, 2013; Hayes, 2011). ACOEM (2011) recommends against routinely providing botulinum injections for tension or cervicogenic headache, based on limited evidence that it may cause harm, and the costs may exceed the benefits.

**Ablative techniques:**

Two systematic reviews identified poor-quality and conflicting evidence of effectiveness of cervical radiofrequency ablation for cervicogenic headache (Falco, 2012; Hayes, 2011). The ACOEM recommends against routinely providing radiofrequency neurotomy to eligible patients, based on intermediate evidence that it is ineffective, or that potential harms and costs outweigh benefits (ACOEM, 2011). The ASA/ASRA (2010) agreed strongly that conventional radiofrequency ablation of the medial branch nerves to the facet joint should be performed for neck pain, based on the results of one RCT.

**Neurosurgery:**
One systematic review identified limited evidence from two prospective, uncontrolled series that suggested temporary relief from discectomy with interbody fusion; while studies included subjects with pain refractory to conventional treatment, no specific characteristics could be identified that were predictive of a positive outcome or sustained response to treatment (Hayes, 2011). The long-term efficacy of surgical procedures for occipital neuralgia or cervicogenic headache has not been established in well-designed clinical trials. Several small retrospective case series with short-term follow-up have reported positive effects using other surgical treatments, including, but not limited to:

- C2 nerve root decompression.
- C2 dorsal root ganglionectomy.
- Decompression followed by ganglionectomy.
- C2 and/or C3 ganglionectomies.
- Neurolysis of the greater occipital nerve.
- Intradural rhizotomies with varying levels of relief and duration.

**Peripheral nerve stimulation:**

Two recent systematic reviews found insufficient evidence of effectiveness of various electrostimulation techniques, including occipital nerve stimulators, for treatment of occipital neuralgia or cervicogenic headache (Kroelig, 2013; Jasper, 2008). Well-designed RCTs comparing neurostimulation to established treatment options or a sham procedure on larger populations with longer follow-up are needed to define the benefits of neurostimulation and electrical stimulation for these indications. The ASA/ASRA (2010) identified no studies related specifically to occipital neuralgia or cervicogenic headache and, therefore, made no specific recommendations for peripheral nerve stimulation for these indications. However, they made the following general recommendations for (ASA/ASRA, 2010):

- Subcutaneous peripheral nerve stimulation in the multimodal treatment of patients with painful peripheral nerve injuries who have not responded to other therapies, based on several observational studies.
- Transcutaneous electrical nerve stimulation as part of a multimodal approach to pain management for patients with chronic back pain, based on a meta-analysis of RCTs.
- Transcutaneous electrical nerve stimulation for other pain conditions (e.g., neck and phantom limb pain) based on observational studies.

**Policy updates:**

We identified one new systematic review and one new evidence-based guideline for this policy. The systematic review found insufficient evidence to support the clinical utility of radiofrequency neurotomy and pulsed radiofrequency ablation for cervicogenic headache (Nagar, 2015). The Congress of Neurological Surgeons recommended occipital neuralgia stimulation as a treatment option for patients with medically refractory occipital neuralgia based on nine small case series (Sweet, 2015). However, they also acknowledged evidence of long-term effectiveness, optimal region for lead placement and
optimal lead type were lacking, and RCTs and other well-designed studies demonstrating the
effectiveness of occipital neuralgia stimulation have been conducted in other populations. The new
information would not change the original conclusions of this policy. Therefore, no changes to the policy
are warranted.

In 2018, we identified one updated systematic review on local injection therapies by Hayes (2017). Their
results are consistent with previous findings, and no policy changes are warranted.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
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<tbody>
<tr>
<td><strong>Hayes (2017)</strong></td>
<td>Key points:&lt;</td>
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<tr>
<td>Local injection therapy for cervicogenic headache and occipital neuralgia</td>
<td>- Systematic review of seven RCTs, one crossover RCT, and two retrospective cohort studies.</td>
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<td>- Interventions: injections with Botulinum Toxin Type A (four studies); local anesthetic plus steroid (three studies); local anesthetic alone (two studies); or local anesthetic plus fentanyl, epinephrine, and clonidine (one study).</td>
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<td>- Comparisons: placebo injections (five studies), radiofrequency ablation (four studies), or occipital neurectomy (one study).</td>
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<tr>
<td></td>
<td>- Overall quality: very low to low.</td>
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<td>- Cervicogenic headache:</td>
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<td>- Botulinum Toxin Type A: inconsistent results of symptom relief.</td>
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<td></td>
<td>- Injection with local anesthetic with or without adjunctive medications: may be more effective than placebo, but not significantly different from radiofrequency ablation.</td>
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<td>- Occipital neuralgia:</td>
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<td></td>
<td>- No difference between Botulinum Toxin Type A and radiofrequency ablation.</td>
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<td></td>
<td>- Injection therapy may be more effective than placebo and same as radiofrequency ablation for pain relief.</td>
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<tr>
<td></td>
<td>- Radiofrequency ablation/neurectomy may be favored more than injections with anesthetic plus steroids for pain relief.</td>
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<tr>
<td></td>
<td>- Mild and transient adverse events. The optimal formulation of anesthetic-based injections, the long-term efficacy and safety of the procedures, and the comparative efficacy and safety of injections versus conservative treatments are uncertain.</td>
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<tr>
<td><strong>Nagar (2015)</strong></td>
<td>Key points:&lt;</td>
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<tr>
<td>Radiofrequency and pulsed radiofrequency for cervicogenic headache</td>
<td>- Systematic review of five non-RCTs and four RCTs.</td>
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<td>- Overall quality: low to moderate. Limited by inconsistencies between RCTs, flaws in trial design, and gaps in the chain of evidence.</td>
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<td>- There is insufficient evidence to support radiofrequency or pulse radiofrequency ablation.</td>
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<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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</table>
| Electrotherapy for neck pain | • Systematic review of 20 small trials (n = 1,239 with neck pain) containing 38 comparisons of various electrotherapy modalities; variable study quality, heterogeneous treatment subtypes, and conflicting results.  
• Limited evidence of no benefit for diadynamic current for reduction of trigger point tenderness in chronic mechanical neck disorders or cervicogenic headache.  
• Unclear or conflicting evidence for direct current for acute or chronic occipital headache.  
• Conclusions: No definite statements on the efficacy and clinical usefulness of electrotherapy modalities for neck pain can be made, and there is uncertainty about effect estimates in pain and other outcomes. |
| Falco (2012) Cervical facet joint interventions | **Key points:**  
• Systematic review identified: one randomized, double-blind, active-controlled trial and one prospective trial for cervical medial branch blocks for cervicogenic headache that were excluded from final analysis due to significant methodological flaws; one randomized sham-controlled, double-blind trial (n = 24) and five uncontrolled studies of radiofrequency neurotomy.  
• Overall quality: low (observational studies) to moderate (RCT).  
• RCT results: found fair evidence of effectiveness of pain reduction lasting from months, to more than one year, for cervical radiofrequency neurotomy for cervicogenic headache.  
• Observational studies found generally positive results, but with significant variation in diagnostic criteria, techniques, outcomes, and patient populations.  
• Reported complications: worsening of pain, burning, or dysesthesia; decreased sensation and allodynia in the skin in the region of the facets denervated; transient leg pain; persistent leg weakness; and inadvertent lesioning of the spinal nerve or ventral ramus resulting in motor deficits, sensory loss, and de-afferentation pain. |
| Hayes (2011) Local injection therapy and neurosurgery for cervicogenic headache and occipital neuralgia | **Key points:**  
• Identified two prospective uncontrolled series.  
• Overall quality: low.  
• Discectomy with interbody fusion: procedure was associated with temporary pain relief: mean duration of improvement was 22.7 months and 14.8 months (range, one month to 58 months) in the two studies.  
• Surgical risks: bleeding and infection, adverse effects associated with anesthesia, accidental damage to associated structures, and scarring.  
• Insufficient evidence to establish definitive patient selection criteria for neurosurgery. Precautions to be taken are similar to those appropriate with these treatments for other diagnoses, including avoiding treatment of patients with serious systemic disease, hematologic disorders, or local infection at the site of treatment. |
| Jasper (2008) Implanted occipital nerve stimulators | **Key points:**  
• Identified 10 observational studies, including four, and a number of case series, case reports for implanted occipital nerve stimulators; no RCTs.  
• Limited evidence of effectiveness: reportedly successful for 70% – 100% of patients. Rapid and significant reduction of pain in patients with occipital headaches and transformed migraine, but less dramatic for patients with cluster headaches. No long-term adverse events occurred. Several short-term incidents occurred including infection, lead displacement, and battery depletion. |
References

Professional society guidelines/other:


Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**


**Local Coverage Determinations (LCDs):**

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>64405</td>
<td>Injection, anesthetic agent; greater occipital nerve</td>
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<tr>
<td>64450</td>
<td>Injection, anesthetic agent, lesser occipital nerve</td>
<td></td>
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<tr>
<td>64533</td>
<td>Percutaneous implantation of neurostimulator electrode array; cranial nerve</td>
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<tr>
<td>64555</td>
<td>Percutaneous implantation of neurostimulator electrode array; peripheral nerve</td>
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<tr>
<td>64615</td>
<td>Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)</td>
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<tr>
<td>64633</td>
<td>Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint</td>
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<td>ICD-10 Code</td>
<td>Description</td>
<td>Comments</td>
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<tr>
<td>M53.81</td>
<td>Other specified dorsopathies, occipito-atlanto-axial region</td>
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<td>M53.82</td>
<td>Other specified dorsopathies, cervical region</td>
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<tr>
<td>M53.83</td>
<td>Other specified dorsopathies, cervicothoracic region</td>
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<td>M54.2</td>
<td>Cervicalgia</td>
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<tr>
<td>M54.81</td>
<td>Occipital neuralgia</td>
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<thead>
<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>J0585</td>
<td>Injection, Onabotulinumtoxina, 1 Unit (for example (Botox ® ) )</td>
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<tr>
<td>J0587</td>
<td>Botulinum toxin type B, per 100 units</td>
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