

Subject: Occipital and Sphenopalatine Ganglion Nerve Block Therapy for the Treatment of Headache and Neuralgia

Document #: SURG.00144

Status: Revised

Publish Date: 09/27/2023

Last Review Date: 08/10/2023

Description/Scope

This document addresses occipital nerve blocks (or blockade) and sphenopalatine ganglion nerve blocks *as a therapy for treatment of headache syndromes*. Occipital nerve block therapy involves injection of a local anesthetic with or without steroid around the greater and lesser occipital nerves located in the back of the head just above the neck area. These occipital nerve block procedures have been studied for the treatment of various headache syndromes and occipital neuralgia. Sphenopalatine ganglion nerve blocks involve intranasal insertion of topical anesthetic to block the sphenopalatine ganglion.

Note: Occipital nerve blockade as a *diagnostic method* for the evaluation of headaches and occipital neuralgia is not included within the scope of this document.

Position Statement

Investigational and Not Medically Necessary:

Occipital nerve block therapy is considered **investigational and not medically necessary** for the treatment of occipital neuralgia and headache syndromes including, but not limited to, chronic migraine, chronic daily headache, cervicogenic and cluster headache.

Sphenopalatine ganglion nerve block therapy is considered **investigational and not medically necessary** for all indications including, but not limited to, the treatment of migraine headaches and non -migraine headaches.

Rationale

According to the ATLAS of Headache Disorders and Resources data, headaches, including migraine and tension-type headache, are among the most prevalent disorders in the world's general population. Worldwide prevalence studies have estimated that one-half to three-quarters of adults aged 18 to 65 years have experienced at least one headache in the previous year. This data reports that over 10% of affected individuals have migraine, and 1.7-4% of the adult population is affected by headache on 15 or more days every month (WHO, 2011).

Chronic Migraine Headache:

In 2015, results of a randomized, multicenter, double-blind, placebo-controlled study were published which measured the effect of greater occipital nerve blockade (GONB) on chronic migraine headaches. Individuals with chronic migraine were randomly divided into two groups of 42. GONB was administered 4 times (once per week) with saline placebo in group A and with bupivacaine in group B. After 4 weeks of treatment, the blinding was removed in group A and GONB was delivered to this placebo group by also using bupivacaine, while group B continued to receive bupivacaine only once per month. The primary endpoint was the difference in number of headache days, duration of headache, and pain scores. After 1 month of treatment, the number of headache days had decreased from 16.9 ± 5.7 to 13.2 ± 6.7 in group A ($p=0.035$) and from 18.1 ± 5.3 to 8.8 ± 4.8 in group B ($p<0.001$) and $p=0.004$ between groups. The duration of headache (in hours) had decreased from 24.2 ± 13.7 to 21.2 ± 13.4 in group A ($p=0.223$) and from 25.9 ± 16.3 to 19.3 ± 11.5 in group B ($p<0.001$), and $p=0.767$ between groups. The visual analog scale (VAS) score decreased from 8.1 ± 0.9 to 6.7 ± 1.6 in group A ($p=0.002$) and from 8.4 ± 1.5 to 5.3 ± 2.1 in group B ($p<0.001$) and $p=0.004$ between groups. After blinding was removed (in months 2 and 3), group A exhibited similar results to group B in month 3. The authors concluded that, in this limited trial, GONB with bupivacaine was superior to placebo and was effective and safe for the treatment of chronic migraine. However, limitations were noted within this small study, which compared GONB vs. saline placebo. Only 72 of the 84 subjects actually completed the study ($n=33$ placebo; $n=39$ bupivacaine). Although treatment with bupivacaine reduced the number of headache days per month, it did not reduce the duration of headaches, compared with placebo. This preliminary study is the first placebo-controlled study of GONB in chronic migraine with only a short duration of follow-up, which was limited to only 1 month of actual blinding and did not address the potential confounder of a placebo effect (Inan, 2015).

Dilli and colleagues conducted a randomized, placebo-controlled study of 63 subjects with chronic migraine where a single treatment of GONB was delivered to 33 individuals in the active treatment arm. The study participants were randomized to receive either 2.5 ml of 0.5% bupivacaine plus 0.5 ml (20 mg) methylprednisolone over the ipsilateral (unilateral headache) or bilateral (bilateral headache) occipital nerve (ON) or 2.75 ml normal saline plus 0.25 ml of 1% lidocaine without epinephrine (placebo arm). In the active and placebo groups respectively, the mean frequency of at least moderate (mean 9.8 versus 9.5) and severe (3.6 versus 4.3) migraine days and acute medication days (7.9 versus 10.0) were not substantially different at baseline. All study subjects completed a 1-month headache diary prior to and after the double-blind injection. The primary outcome measure was defined as a 50% or greater reduction in the frequency of days with moderate or severe migraine headache in the 4-week post-injection study period, compared to the 4-week pre-injection baseline period. At 28 days post-injection, the percentage of subjects with at least a 50% reduction in the frequency of moderate or severe headache days was 30% for both groups (10/30 vs. 9/30, 0.00, 95% confidence interval [CI], -0.22 to 0.23). The authors concluded that GONB does not reduce the frequency of moderate to severe migraine days in individuals with episodic or chronic migraine compared to placebo. However, this study did not evaluate the onset or duration of benefit of the GONB; it also did not evaluate the acute response to the injection. Not all trial subjects were experiencing headache pain at the time of injection. The authors acknowledged the need for a placebo-controlled trial to evaluate GONB for acute relief of migraine pain (Dilli, 2015).

Another randomized comparative study was conducted to determine whether adding triamcinolone to local anesthetics increased the efficacy of GONB and trigger-point injections (TPIs) for chronic daily headache (transformed migraine [TM]). The study subjects with TM were randomized to receive GONB and TPIs using lidocaine 2% and bupivacaine 0.5% with either saline (group A) or triamcinolone 40 mg (group B). The severity of headache and associated symptoms were assessed before and 20 minutes after injection for 37 individuals with TM. The study subjects documented headache and severity of associated symptoms for 4 weeks after injections. Changes in symptom severity were then compared between the two groups. Twenty minutes after injection, the mean headache severity had decreased by 3.2 points in group A ($p<0.01$) and by 3.1 points in group B ($p<0.01$) with a mean neck pain

severity decrease by 1.5 points in group A ($p < 0.01$) and 1.7 points in group B ($p < 0.01$). The mean duration of headache-free time was reported as 2.7 ± 3.8 days in group A and 1.0 ± 1.1 days in group B ($p = 0.67$). None of the outcome measures differed significantly between the two groups. The authors concluded that the addition of triamcinolone to local anesthetics when performing GONB and TPIs was not associated with improved outcome (Ashkenazi, 2008).

Additional case series have reported similar results including one series that reported on 19 subjects with chronic migraine and mechanical brush allodynia (BA) who were treated with GONB with or without TPI. Allodynia was evaluated using a structured questionnaire and by applying a 4 x 4-inch gauze pad to skin areas in the trigeminal and cervical dermatomes. The degree of allodynia ("Allodynia score") was measured on a 100-mm VAS before treatment and 10 and 20 minutes thereafter. Headache levels were assessed using an 11-point verbal scale. Allodynia scores and headache levels before and after treatment were compared. Twenty minutes after treatment, headache was reduced in 17 subjects (89.5%) and did not change in 2 (10.5%). The average headache level was 6.53 before treatment and 3.47 at 20 minutes after treatment. The average allodynia score decreased after 20 minutes in all study subjects. The average allodynia score per site was reduced by 18.69 mm and 13.74 mm in the trigeminal and cervical areas, respectively. In this very small series, the authors concluded that there was a positive correlation between allodynia index obtained through the questionnaire and allodynia score obtained by examination and that GONB with or without TPI reduced both headache and BA in this migraine group. However, multiple confounders limit the reported conclusions of this series. These include lack of a sham control comparator and the fact that all participants were also on preventive medications during the study. These included antidepressants, anticonvulsants, antipsychotics, muscle relaxants and non-steroidal anti-inflammatory drugs (NSAIDs) with a rate of 2.82 drugs per trial subject. Other limitations include heterogeneity of the study population, the fact that some subjects had TPI in addition to GONB and some were over-using acute pain medications at the time of testing (Ashkenazi, 2005).

A single practice case review reflected a therapeutic partial response from GONB on chronic headache syndromes, including migraine and cluster headaches which lasted a median timeframe of 21 days in cluster (for 13 of 22 injections) and 30 days for chronic migraine headaches (for 26 of 57 injections) (Afridi, 2006).

A 2020 randomized controlled study by Chowdhury and colleagues reported on the efficacy and tolerability of combined chronic migraine treatment with GONB with topiramate compared to monotherapy with topiramate. Participants received one of three treatment arms; group A consisted of topiramate monotherapy once per day, group B consisted of topiramate plus GONB with 40 mg lidocaine (2%) and 80 mg (2 ml) methylprednisolone as the first injection followed by 2 monthly injections of lidocaine. Group C participants received topiramate plus monthly GONB with 40 mg lidocaine (2%) injections for 3 months. The primary efficacy endpoint was the mean change in monthly migraine days. A secondary endpoint was the number of participants who achieved more than 50% reduction in monthly headache days from baseline to 3 months. There were 125 randomized participants; 41 to group A, 44 to group B, and 40 to group C. Efficacy assessments were done for 121 participants. Participants who received combination therapy and GONB in groups B and C showed greater reductions in monthly migraine days at month 3 compared to those in group A who received monotherapy only. The absolute mean monthly migraine days changed from 14.1 days at baseline to 6.7 days at month 3 in group A compared to 12.9 days to 4 days in group B and 15 days to 4.2 days in group C. At the end of month 3, 30/42 participants (71.4%) in group B and 24/38 participants (62.4%) in group C achieved a greater than 50% reduction in monthly headache days. This compared to 16/41 participants (39%) with greater than 50% improvement in group A. There were some mild treatment-emergent adverse events reported. These included limb paresthesias, local site swelling, bleeding, and dizziness. No serious adverse events were reported. In this study, lack of investigator blinding, and lack of a placebo arm (sham injections) created risks for bias. Further study is needed to confirm this study's findings.

Sphenopalatine Ganglion Blocks

Sphenopalatine ganglion nerve blocks (SPG) have also been proposed for treatment of headaches. In a double-blind, parallel-arm, placebo-controlled randomized study (Cady, 2015a), the authors reported the results of repetitive SPG block with anesthetic as a treatment for chronic migraine compared to saline. There were 41 participants initially randomized 2:1 to receive either an anesthetic agent ($n = 27$) or saline ($n = 14$). In the saline group, 1 participant withdrew from the study citing lack of efficacy. With 40 participants completing the treatment, efficacy was measured using the numeric rating scale (NRS) and, at two of the visits, by using a Headache Impact Test (HIT-6) questionnaire. There were 2 participants in the saline group and 1 participant in the SPG block group removed from data analysis due to protocol violations. The NRS score was assessed at baseline and at 15 minutes, 30 minutes, and 24 hours after treatment. Participants in the active treatment group received 12 SPG blocks while those in the sham group received saline twice per week for 6 weeks. Participants were re-evaluated at 1 and 6 months after their final treatment. For those in the active treatment group, the pre-treatment NRS mean score was 3.18, 2.53 after 15 minutes, 2.41 after 30 minutes, and 2.85 after 24 hours. For the sham group, pre-treatment NRS mean score was 3.78, 3.51 after 15 minutes, 3.45 after 30 minutes, and 4.20 after 24 hours. HIT-6 scores were decreased in those receiving active treatment from before treatment to the final treatment compared to the sham group. Adverse events were reported as mild to moderate and included lacrimation, unpleasant taste and mouth numbness. These adverse events may suggest that blinding was not maintained for all participants. The primary end point was not statistically different when comparison was made between those who experienced adverse events and those who did not. There were no controls for usage of abortive therapies prior to the study intervention. The authors characterized the study as "exploratory" in nature and noted that "Further research on the efficacy, optimal frequency, and numbers of repetitive SPG blockade is warranted."

Using the same population as the Cady, 2015a study above, Cady and colleagues (Cady, 2015b) reported on sustained post-treatment outcomes (6-month outcomes) for secondary end points. Participants were assessed for change in the number of headache days from baseline to 1 month post treatment. Comparisons were also made for average pain, general activity, mood, normal work interference, and HIT-6 scores at 6 months post treatment. While some improvements were reported, there were no statistically significant differences in secondary end points between the treatment group and the sham group. The authors note "a more complete study of this novel treatment modality is warranted, as well as more studies to determine the role of the SPG in the physiology in migraine and its treatment."

A 2022 Systematic Review and Practice Guideline for Percutaneous Interventional Strategies for Migraine Prevention published by the American Academy of Pain Medicine (Barad, 2022) concluded due to a very low certainty of evidence, SPG blocks received a weak recommendation for chronic migraine prevention.

Post-Dural Puncture Headache

In 2020, Jespersen and colleagues reported the results of the use of SPG treatment for post-dural puncture headache. In this blinded, randomized clinical trial, 40 participants with post-dural puncture headache received either SPG block with local anesthetic ($n = 20$) or saline ($n = 20$). Primary outcome was measured using a 100 mm VAS score assessed at 30 minutes after SPG block. Secondary outcomes included: a) intensity of pain in the upright position at 1 hour and 7 days after SPG block; b) intensity of pain in the supine position at 30 minutes, 60 minutes and 7 days after SPG block; c) frequency of participants with a pain intensity less than 30 mm in the upright position at 30 min after SPG block; and d) the frequency of participants who received rescue SPG block or epidural blood patch. Pain intensity in the upright position 30 min after the block was 26 mm in the local anesthetic group versus 37 mm in the saline group. There were no significant differences in pain intensity at 60 min and 1 week after the block. The frequency of participants with pain intensity less than 30 mm at 30 min after SPG block was 12/20 (60%) in the local anesthetic group and 9/20 (45%) in the

placebo group. In the local anesthetic group, during the time frame from 1 hour to 7 days after the block, 13/20 participants (65%) received a rescue block, and 10/20 (50%) received an epidural blood patch. In the placebo group, during the time frame from 1 hour to 7 days after the block, 13/20 (65%) received a rescue block and 9/20 (45%) received an epidural blood patch. Reported adverse events (by 10 participants) included severe nasal discomfort and nausea during treatment, light pain or discomfort during treatment, throat discomfort, ear pain, and tingling in the cheek. There were no statistically significant differences in pain intensity between the two groups. Noting a more than 40 mm VAS reduction of pain in both the active therapy and placebo groups, the authors proposed that the treatment effect may not have been related to the local anesthesia injection.

In 2021, the American Society of Anesthesiologists published their statement on Post-Dural Puncture Headache stating "There is currently insufficient evidence to recommend the use of acupuncture, greater occipital nerve blocks, sphenopalatine ganglion blocks, epidural morphine, and prophylactic intrathecal morphine via an intrathecal catheter after UDP in the treatment of obstetric PDPH."

Cluster Headache:

The evidence of benefit of GONB in the management of cluster headache is limited to case series showing only temporary symptomatic relief. Results of these case series varied in terms of frequency, intensity and duration of headache relief. Further study is needed (Gantenbein, 2012; Peres, 2002).

Cervicogenic Headache:

A randomized, double-blind, sham-controlled trial evaluated the effectiveness of nerve stimulator-guided ONB therapy in the treatment of cervicogenic headache. The reduction in analgesic consumption was the primary outcome measure. Fifty adult subjects diagnosed with cervicogenic headache were randomly divided into two equal groups of 25 each. All trial participants in both groups received greater and lesser ONB, whereas only 16 subjects in each group received facial nerve blockade in association with the occipital blocks. The control group received injections of an equivalent volume of preservative-free normal saline. Pain was assessed using the VAS and the Total Pain Index. A total of 47 subjects entered into the final analysis because 3 subjects were lost to follow-up. Anesthetic ONB was effective in reducing the VAS and the Total Pain Index by approximately 50% from baseline values ($p=0.0001$). Analgesic consumption; duration and frequency of headache; nausea; vomiting; photophobia; phonophobia; decreased appetite; and limitations in functional activities were significantly less in the treated block group compared to the control group ($p<0.05$). It was noted that the nerve stimulator technique for nerve localization enabled the operator to determine the exact location of the nerve, thereby increasing the chance for success. However, while use of the nerve stimulator technique improved the accuracy of ONB, it required the individual's co-operation for optimal detection of the nerve. For this reason, effectiveness might not always be initially achieved, making repeated blocks necessary to increase the likelihood of success. Limitations of this study included the short duration of outcomes data with follow-up of only 2 weeks and difficulty in blinding due to numbness which was experienced by the treated study group who received the anesthetic blockade (Naja, 2006).

Despite preliminary results from limited trials demonstrating some efficacy for use of GONB in chronic headache syndromes, a review about cervicogenic headaches noted, "Because of the risks associated with these procedures (GONB) and the lack of well-controlled outcomes studies, more conservative interventions are typically prescribed" (Page, 2011).

Occipital Neuralgia:

According to the American Association of Neurological Surgeons (AANS), occipital neuralgia is a distinct headache syndrome classified as primary or secondary in etiology. Secondary headaches are usually associated with an underlying disease that may include tumor, trauma, infection, systemic disease or hemorrhage. Structural and neurologic abnormalities, as well as chronic neck tension and nerve pinching from overly tight neck muscles and nerve compression due to osteoarthritis or lesion, are all known causes of occipital neuralgia. In some cases, no cause can be isolated. Accurate diagnosis and treatment of the underlying condition often eliminates the headache. Magnetic resonance imaging (MRI) and computed tomography (CT) imaging are often used to diagnose occipital neuralgia following abnormal findings on a neurological examination. A positive response (that is, relief of pain) to an anesthetic nerve block can confirm the diagnosis.

The AANS has stated:

Often, occipital neuralgia symptoms will improve or disappear with heat, rest, physical therapy including massage, anti-inflammatory medications, and muscle relaxants... Percutaneous nerve blocks may not only be helpful in diagnosing occipital neuralgia, but can also help alleviate pain. 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 repeat blocks using steroids may cause serious adverse effects (AANS, 2013).

Regarding the efficacy of GONB therapy for the treatment of occipital neuralgia, efficacy has only been demonstrated in observational and cohort studies and series of small numbers with only short-term outcomes data. Given that there is no conclusive evidence of the durable therapeutic effect of GONB in occipital neuralgia, further study is needed to confirm its benefits when closely balanced with risk, before widespread use can be recommended (Bogduk, 2009; Hammond, 1978; Vanelderden, 2010).

Background/Overview

The International Classification of Headache Disorders (ICHD) lists migraine as a primary headache. A primary headache is one that is not associated with any demonstrable organic disease, or structural or neurologic abnormality. Migraines may be unilateral or bilateral. They may occur with or without a preceding aura, such as dizziness, tinnitus, photophobia, or visual scintillations (for example, bright zigzag lines). Migraines manifest as a recurring attack usually lasting for 4-72 hours and involving pain of moderate to severe intensity, often with nausea, sometimes vomiting, sensitivity to light and/or sound and other sensory stimuli. Migraines are present in about 28 million people in the United States.

GONB or nerve block therapy has been proposed as a treatment of medically intractable chronic headache types, including migraine, cluster, cervicogenic and occipital neuralgia, using locally injected anesthetics with or without the addition of corticosteroid preparations. To date, the published evidence regarding the use of ONB therapy as a treatment option for chronic headache syndromes, including occipital neuralgia, has been largely limited to case series and individual case reports at single institutions and headache centers. Some preliminary studies investigating the use of ONB therapy as a treatment for occipital neuralgia and chronic headaches have shown some improvement in pain management for some individuals (ranging widely from no relief to hours or weeks/months of pain relief). Additional randomized, placebo-controlled, prospective studies with larger test populations and longer follow-up periods are needed, before conclusions regarding the safety and efficacy of this technique can be made (Dinakar, 2016; Peters, 2004; Chavin, 2003). Limited published evidence has not demonstrated consistent clinical utility for ONB therapy in the management of headache syndromes (Govindappagari, 2014; Levin, 2010; Santos, 2017).

Definitions

Afferent: A nerve that carries impulses toward the central nervous system (CNS). The opposite of an afferent nerve is an efferent nerve that carries impulses away from the CNS.

Aura: Symptoms, such as disturbances in vision, smell or perception, that occur prior to a migraine headache and that often indicate the impending occurrence of a migraine headache.

Cervicogenic Headache: Pain referred to the head from the upper cervical vertebrae and muscles, which manifests as chronic hemicranial pain usually beginning in the suboccipital region and spreading anteriorly to the ipsilateral orbital, frontal, and temporal areas. This headache, of almost daily occurrence, is typically dominant on one side, but may occasionally be bilateral.

Cluster Headache: Sudden, intensely painful headaches that occur repeatedly in groups or clusters.

Ganglion: A group of neuron cell bodies in the peripheral nervous system. Ganglia provide relay points and intermediary connections between different neurological structures in the body, such as the peripheral and central nervous systems.

Intractable: Having no relief, such as a symptom or a disease that is not relieved by therapeutic measures.

Migraine: A vascular headache believed to be caused by blood flow changes and certain chemical changes in the brain leading to a cascade of events that include constriction of the arteries supplying blood to the brain with resultant severe headache, stomach upset, and visual disturbances, (referred to as aura). Sensitivity to light is also commonly associated with these headaches.

Nociceptive: The ability of specific portions of the nervous system to sense and transmit painful stimuli.

Nummular Headache: A rare headache disorder characterized by focal and well-circumscribed pain fixed within a rounded or oval/elliptical-shaped area of the head, typically 2 to 6 cm in diameter, which most commonly affects the parietal region and is almost always unilateral and side-locked. The pain is typically characterized as pressure-like, sharp, or stabbing and is usually mild to moderate in intensity. This disorder may be episodic or chronic with distortions of sensation including hyperesthesia, hypoesthesia, allodynia, and paresthesias frequently reported in the affected area.

Occipital Nerves: Spinal nerves; the greater occipital nerve arises from between the first and second cervical vertebrae, along with the lesser occipital nerve.

Occipital Neuralgia: This distinct type of headache is caused by irritation or injury to the greater or lesser occipital nerves. Occipital neuralgia is characterized by piercing, throbbing, or electric shock-like chronic pain in the upper neck, back of the head, and behind the ears, usually on one side of the head. Some individuals also experience pain in the scalp, forehead, and behind the eyes.

Sphenopalatine ganglion: a small structure of nerve cells located behind the bony structures of the nose. This bundle of nerves is associated with the trigeminal nerve which is involved in headache disorders.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

64405	Injection(s), anesthetic agent(s) and/or steroid; greater occipital nerve [when specified as a therapeutic nerve block]
64450	Injection(s), anesthetic agent(s) and/or steroid; other peripheral nerve or branch [when specified as a therapeutic nerve block of lesser occipital nerve]
64505	Injection, anesthetic agent; sphenopalatine ganglion [when specified as a therapeutic nerve block]

ICD-10 Diagnosis

G43.001-G43.E19	Migraine
G44.001-G44.89	Other headache syndromes
G97.1	Other reaction to spinal and lumbar puncture
M54.81	Occipital neuralgia
R51.0-R51.9	Headache

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Revised	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Changed title to "Occipital and Sphenopalatine Ganglion Nerve Block Therapy for the Treatment of Headache and Neuralgia". Added INV/NMN statement for sphenopalatine ganglion nerve blocks. Updated the Description/Scope, Rationale, Background/Overview, References and Index sections. Updated Coding section with 10/01/2023 ICD-10-CM changes, added G43.E19 to end of range; also added CPT 64505 and ICD-10-CM diagnosis G97.1.
Reviewed	08/11/2022	MPTAC review. References were updated.
Reviewed	08/12/2021	MPTAC review. References were updated.
Reviewed	08/13/2020	MPTAC review. The Background, Definitions and References sections were updated. Updated Coding section with 10/01/2020 ICD-10-CM changes, R51.0-R51.9 replacing R51.
	12/31/2019	Updated Coding section with 01/01/2020 CPT changes; revised descriptors.
Reviewed	08/22/2019	MPTAC review. References were updated.
Reviewed	09/13/2018	MPTAC review. References were updated.
Reviewed	11/02/2017	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." References were updated.
Reviewed	11/03/2016	MPTAC review. The Rationale, Coding and References sections were updated.
New	08/04/2016	MPTAC review. Initial document development.

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