

7.01.135	Surgical Deactivation of Headache Trigger Sites	
Section 7.0 Surgery	Effective Date September 30, 2014	
Subsection	Original Policy Date September 30, 2014	Next Review Date September 2015

Description

Surgical deactivation of trigger sites is a proposed treatment of migraine headaches. The procedure involves identifying a patient’s predominant migraine trigger site and transecting the branches of the trigeminal nerve supplying that area of head and neck. The treatment is based on the theory that migraine headaches arise due to inflammation of trigeminal nerve branches in the head and neck caused by irritation of the surrounding structures. The technique could potentially be used to treat other types of headache.

Related Policies

- Occipital Nerve Stimulation

Policy

Surgical deactivation of trigger sites is considered **investigational** for the treatment of migraine and non-migraine headache.

Policy Guidelines

International Headache Society (IHS) Classification II criteria¹:

Migraine without aura

Description

Recurrent headache disorder manifesting in attacks lasting 4 to 72 hours. Typical characteristics of the headache are unilateral location, pulsating quality, moderate or severe intensity, aggravation by routine physical activity, and association with nausea and/or photophobia and phonophobia.

Diagnostic criteria

- A. At least 5 attacks fulfilling criteria B-D
- B. Headache attacks lasting 4 to 72 hours (untreated or unsuccessfully treated)
- C. Headache has at least 2 of the following characteristics:
 - 1. Unilateral location

2. Pulsating quality
 3. Moderate or severe pain intensity
 4. Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs)
- D. During headache at least 1 of the following:
1. Nausea and/or vomiting
 2. Photophobia and phonophobia
- E. Not attributed to another disorder

1.2 Migraine with aura

Description:

Recurrent disorder manifesting in attacks of reversible focal neurologic symptoms that usually develop gradually over 5 to 20 minutes and last for less than 60 minutes. Headache with the features of migraine without aura usually follows the aura symptoms. Less commonly, headache lacks migrainous features or is completely absent.

Diagnostic criteria:

- A. At least 2 attacks fulfilling criterion B
- B. Migraine aura fulfilling criteria B and C for one of the subforms 1.2.1-1.2.6
- C. Not attributed to another disorder

Coding

There is no specific CPT code for this procedure but it might be reported using one of the following:

- 15824 Rhytidectomy; forehead
- 15826 Glabellar frown lines
- 30130 Excision inferior turbinate, partial or complete, any method
- 30140 Submucous resection inferior turbinate, partial or complete, any method
- 30520 Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
- 64716 Neuroplasty and/or transposition; cranial nerve (specify)
- 67900 Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as

investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Rationale

Background

Migraine is a common headache disorder with a prevalence in the United States of approximately 18% in women and 6% in men.² According to the International Headache Society, migraine headache is a recurrent disorder with attacks lasting 4 to 72 hours. Typical features of migraine headaches include unilateral location, pulsating quality, moderate or severe intensity and associated symptoms such as nausea, photophobia, and/or phonophobia.¹

A variety of medications are used to treat acute migraine episodes. These include medications that are taken at the outset of an attack to abort the attack (triptans, ergotamines), and medications to treat the pain and other symptoms of migraines once they are established (nonsteroidal anti-inflammatory drugs, narcotic analgesics, antiemetics). Prophylactic medication therapy may be appropriate for people with migraines that occur more than 2 days per week. In addition to medication, behavioral treatments such as relaxation and cognitive therapy are used in the management of migraine headache. Moreover, botulinum toxin A injections are a U.S. Food and Drug Administration (FDA)-approved treatment for chronic migraine (migraines occurring on at least 15 days per month for at least 3 months).

Surgical deactivation of trigger sites is another proposed treatment of migraine headaches. The procedure was developed by plastic surgeon Bahman Guyuron, MD, following observations that some patients who had cosmetic forehead lifts often reported improvement or elimination of migraine symptoms postsurgery.^{3,4} The procedure is based on the theory that migraine headaches arise due to inflammation of trigeminal nerve branches in the head and neck caused by irritation of the surrounding musculature, bony foramen, and perhaps fascia bands. Accordingly, surgical treatment of migraines involves removing the relevant nerve sections, muscles, fascia and/or vessels. The treatment is also based on the theory that there are specific migraine trigger sites and that these can be located in individual patients. In studies conducted by Dr. Guyuron's research group, clinical evaluation and diagnostic injections of botulinum toxin have been used to locate trigger sites. The specific surgical procedure varies according to the patient's migraine trigger site. The surgical procedures are performed under general anesthesia in an ambulatory care setting and take an average of 1 hour.

Surgical procedures have been developed at 4 trigger sites; frontal, temporal, rhinogenic, and occipital. Frontal headaches are believed to be activated by irritation of the supratrochlear and suborbital nerves by glabellar muscles or vessels. The surgical procedure involves removal of the glabellar muscles encasing these nerves. Fat from the upper eyelid is used to fill the defect in the muscles and shield the nerve. Temporal headaches may be activated by inflammation of the zygomatico-temporal branch of the trigeminal nerve by the temporalis muscles or vessels adjacent to the nerve. To treat migraines located at this trigger site, a segment (approximately 2.5 cm) of the zygomatico-temporal branch of the trigeminal nerve is removed endoscopically. Paranasal headaches may involve intranasal abnormalities, e.g., deviated septum, which may irritate the end branches of the trigeminal nerve. Surgical treatment includes septoplasty and turbinectomy. Finally, occipital headaches may be triggered by irritation of the occipital nerve by the semispinalis capitis muscle or the occipital artery.

Surgery consists of removal of a segment of the semispinalis capitis muscle medial to the greater occipital nerve approximately 1 cm wide and 2.5 cm long, followed by insertion of a subcutaneous flap between the nerve and the muscle to avoid nerve impingement.

It has been proposed that other types of headaches, e.g., tension headaches, may also be triggered by irritation of the trigeminal nerve. Although this mechanism of action is less well-established for headaches other than migraine, it is possible that surgical treatment of trigger sites may also be beneficial for some non-migraine headaches.

Regulatory Status

Not applicable.

Rationale

Literature Review

Assessment of efficacy for therapeutic intervention involves a determination of whether the intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition.

Headache research involves evaluating subjective outcomes e.g., pain intensity and duration. As a result blinded, sham-controlled RCTs are particularly important in determining efficacy above the placebo effect.

Migraine headache

RCTs

To date, 2 RCTs, both from the same research group, have been published evaluating surgical deactivation of migraine headache trigger sites. A description of these RCTs is as follows:

An initial RCT evaluating surgical deactivation of migraine trigger sites was published by Guyuron et al in 2005; this study was not blinded and did not include a sham control.⁵ Eligibility including a diagnosis of migraine headache according to International Classification of Headache Disorders II (ICHD-II) criteria. A total of 100 patients were assigned to the treatment group and 25 to the control group in a 4:1 allocation. They received up to 3 injections of botulinum toxin A (Botox), 1 at each of their most common trigger sites, to identify a predominant site of headache trigger and potential response to treatment. To be considered candidates for surgery, patients needed to have at least a 50% reduction in symptoms for 4 weeks after a botulinum toxin A injection. Patients in the control group received saline injections instead of botulinum toxin A and were not eligible for surgery; for the remainder of the treatment period, they received usual care. For patients in the intervention group, surgery varied by trigger site. In patients with predominantly frontal trigger migraine headache, the glabellar muscle group was removed to relieve compression of the supraorbital and supratrochlear nerves. Patients with temporal migraine headache underwent removal of 3 cm of the zygomatico-temporal branch of the trigeminal nerve. Patients with both temporal and frontal migraine headaches underwent both procedures. Patients with occipital migraine headache underwent removal of a portion of the semispinalis capitis muscles surrounding the occipital nerve, and a subcutaneous flap was used to shield the nerve

from the muscle. Finally, patients with migraine headaches triggered from the septum and turbinates underwent septoplasty and inferior and/or middle turbinectomies.

Among patients assigned to the treatment group, 91 responded to botulinum toxin A injection and underwent surgery and 89 of 100 (89%) completed the 12-month follow-up. Nineteen of 25 (76%) patients in the control group were evaluated at 12 months. A total of 17 of 125 (14%) randomized patients were excluded from the analysis. In a *per protocol* analysis at 12 months, 82 of 89 (92%) patients in the treatment group and 3 of 19 (16%) in the control group experienced significant improvement, defined as at least a 50% reduction in baseline migraine frequency, intensity, or duration. The difference between groups was statistically significant, $p < 0.001$. Thirty-one (35%) of patients in the treatment group and none in the control group reported complete elimination of migraines. Most adverse events following surgery were minor and transient. The most commonly reported events were temporary nasal dryness ($n=12$) and rhinorrhea ($n=11$). Seven patients experienced intense scalp itching that lasted a mean of 6 months.

Five-year outcomes for patients in the treatment group were reported by Guyuron et al in 2011.⁶ Follow-up data were available for 79 patients (87% of those who underwent surgery and 79% of those randomized to this group). Outcomes were reported for 69 patients. The other 10 had received additional migraine headache surgery and were excluded from the analysis. At 5 years, 20 of 69 (29%) reported complete elimination of migraine headache, 41 (59%) reported a significant decrease in symptoms, and 8 (12%) reported no significant change. All measured variables improved significantly at 5 years compared with baseline. For example, mean headache frequency per month decreased from 10.9 to 4.0 ($p < 0.0001$). Long-term data were not reported for patients assigned to the control group.

Limitations of the 2005 RCT include lack of blinding, lack of a sham-control, and randomization before determining eligibility for surgery. In addition, findings were not reported separately by surgical procedure. In terms of long-term follow-up, 5-year data were reported only for the treatment group; long-term outcomes compared with the control group are not available.

In 2009, Guyuron et al published a double-blind, sham-controlled trial evaluating surgical deactivation of migraine trigger sites in 76 patients.³ Eligibility criteria included a diagnosis of migraine headache according to ICHD-II criteria¹ and headaches triggered from a single or predominant site, as determined by a headache diary and physical examination. Participants were then given an injection of botulinum toxin A (Botox) at the prominent site from which migraine pain started. Patients who had a positive response to botulinum toxin A (i.e., at least a 50% decrease in headache symptoms) and in whom headaches recurred after the effect of the botulinum toxin A disappeared were eligible for randomization. The methodology differed from that of the 2005 RCT, previously described, which randomized patients before receiving diagnostic botulinum toxin A injections. In addition, it is worth noting that in 2012, Liu et al (Dr. Guyuron was a coauthor of this study) published an analysis further investigating the method of botulinum toxin injections to select patients for deactivation surgery and found that outcomes were similar in migraine surgery patients who did and did not undergo diagnostic Botox injections.⁴ The Liu et al analysis raises questions about the need for the complex patient selection process used in the published RCTs.

In the 2009 RCT, participants were stratified by the predominant site from which headaches were triggered; frontal, temporal, or occipital, and were then randomized on a 2:1 basis to receive active or sham surgery. A total of 317 participants were screened for inclusion, 130 received botulinum toxin A injections and, based on their response to the injections, 76 were considered eligible to participate and underwent randomization.

In each of the 3 active treatment groups, surgery consisted of exposure and removal of nerves and/or muscles. For patients in the sham group, surgery was limited to exposing the nerves and/or muscles; the integrity of the structures was left intact. The procedures differed according to the predominant headache trigger site and were similar to procedures used in the Guyuron et al 2005 trial. Briefly, patients in the frontal active surgery group underwent removal of the glabellar muscles encasing the supraorbital and supratrochlear nerves. Patients in the temporal active surgery group underwent removal of a segment of the zygomaticotemporal branch of the trigeminal nerve. In the occipital surgery group, a segment of the semispinalis capitis muscle medial to the greater occipital nerve was removed.

Patients kept headache diaries and were seen at 3, 6, 9, and 12 months after surgery. Seventy-five of 76 patients (49 in the active treatment group and 26 in the sham group) completed the 1-year follow-up. There were 29 patients in the frontal group (19 active treatment, 10 sham), 28 in the temporal group (19 active treatment, 9 sham), and 18 in the occipital group (11 active treatment, 7 sham). Patients remained blinded to their group assignment through 12 months, at which time patients in the sham surgery group were offered the operation. Key results are displayed in the following table. Note that for the frequency, intensity, and duration variables, there were no statistically significant differences by trigger site, so overall results are displayed. Results for the same outcomes from the Guyuron et al 2005 RCT are also summarized next.

Baseline data and 12-month change from baseline data

Outcome Variables	Guyuron et al (2009)			Guyuron et al (2005)		
	Active Surgery (n=49)	Sham Surgery (n=26)	p ^b	Active Surgery (n=89)	Usual Care (n=19)	p ^b
Complete elimination of headaches	28/49 (57.1%)	1/26 (3.8%)	<0.001	31/89 (35%)	0/19 (0%)	<0.001
Significant improvement ^a	41/49 (84%)	15/26 (58%)	0.005	82/89 (92%)	3/19 (16%)	<0.001
Mean headache frequency, /mo Baseline 12 mo ^c	9.9 (SD=6.0) 7.4 (SD=5.8)	9.5 (SD=4.4) 3.5 (SD=5.4)	0.005	10.9 (SD=0.8) 3.8 (SD=0.4)	9.9 (SD=1.7) 10.2 (SD=1.7)	<0.001
Mean headache intensity (1-10 VAS) Baseline 12 mo ^c	6.2 (SD=1.7) 3.0 (SD=3.5)	5.5 (SD=1.4) 1.3 (SD=2.9)	0.03	8.6 (SD=0.13) 4.0 (SD=0.3)	8.8 (0.24) 7.0 (0.3)	<0.001
Mean headache duration, days (2009), hours (2005) Baseline 12 mo ^c	0.5 (SD=0.6) 0.3 (SD=0.5)	1.7 (SD=5.6) 0.9 (SD=4.5)	0.43	1.4 (SD=0.14) 0.4 (SD=0.05)	1.3 (SD=0.25) 1.0 (SD=0.2)	0.007

VAS: visual analog scale.

^a Significant improvement was defined as at least a 50% reduction in migraine frequency, intensity, or duration compared with baseline.

^b Between-group p values.

^c In 2009 study, results are reported as change from baseline.

In the 2009 study, in addition to the between-group differences, there was statistically significant improvement in headache frequency, intensity, and duration from baseline to 12 months within the active surgery group and significant improvement in headache frequency and intensity within the sham surgery group. The improvement in outcomes within the sham group were greater than those seen after usual care in the 2005 RCT, suggesting that there may be a substantial placebo effect associated with the surgery to deactivate trigger sites.

No adverse events were reported in the sham surgery group. All patients in the active treatment group reported some degree of paresthesia immediately after the operation. One patient experienced numbness 12 months after the operation. The most common adverse event in the active treatment group was temporal hollowing in 10 of 19 (53%) patients in the T (temporal) group.

Advantages of the 2009 study included a sham control group and blinded comparison of outcomes in the 2 groups through 12 months after surgery. Limitations of the study include small numbers of patients in each subgroup and a lack of reporting of patients' use of other migraine treatments e.g., Botox, medications, etc. during the 12-month follow-up period. In addition, patient selection involved a long multicomponent selection process, which might not be practical on a widespread basis.

A 2014 review article critically evaluating the RCTs on surgical deactivation of migraine trigger sites included the following points⁷:

- The authors of the sham-controlled trial did not mention patients' use of other headache treatments. Postoperative use of medications could have resulted in a reduction in headache frequency; these cases would have been counted as a surgical success in the study.
- In the sham-controlled trial, baseline headache frequency was 9.9 migraines per month in the intervention group and 9.5 migraines per month in the control group and, therefore, the reduction of a small number of migraine episodes per month (which may not be clinically significant) could be considered a surgical success based on the author's criterion of a 50% decrease in frequency.
- Use of the terminology "migraine headaches per month" does not provide information on the number of days per month with migraine headaches or the number of nonmigraine headaches per month.
- Patients in the sham group may have guessed their group assignment because of retained movement of the corrugator supercillii, depressor supercillii and procerus muscles. This could have biased their responses to subjective outcome questions.
- Botox injections are a nonspecific screening tool and can lead to false positives when used to select patients for migraine surgery because Botox injections into the peripheral nerves may also modulate pain at central targets.

Case series

Other research groups have published retrospective case series evaluating some type of surgical deactivation of trigger sites for patients with migraine headache, but no controlled studies. For example, in one of the larger series, Dirnberger and Becker in Austria reported on 60 patients with migraine headache diagnoses meeting International Headache Society criteria.⁸ Patients all underwent resection of the corrugator supercillii muscle by the same surgeon who used the technique recommended by Guyuron. At 6 months, 35 of 60 (58%) reported at least a 50% reduction in headache days and at least a 50% reduction in headache medication use. Twenty patients (33.3%) reported no reduction in headache days at 6 months.

Another relatively large series, published in 2013 by Ducic et al, reported on patients who had undergone surgical decompression of the greater, lesser, and dorsal occipital nerves for chronic migraine following a positive response to botulinum toxin A.⁹ A total of 71 of 108 patients (66%) responded to a follow-up survey. The mean length of follow-up was 33 months. Clinical success, defined as at least a 50% reduction in the migraine headache index (MHI), was achieved in 50 of the 71 respondents (70.4%). Twenty-nine patients (41% of respondents) had a 90% or greater reduction in the MHI. In addition to a lack of a control group, the Ducic data are limited by a low response rate; clinical outcomes in over 30% of patients who underwent surgery are unknown.

Moreover the research group headed by Guyuron has published several retrospective case series that included patients who underwent surgical deactivation of migraine headache trigger sites.¹⁰⁻¹³ Most recently, in 2014 Kurlander and colleagues conducted a chart review of 246 patients who had received migraine surgery by a single surgeon (Dr Guyuron) and had been followed for at least 1 year after surgery.¹³ Mean follow-up was 3.2 years (range 1 to 10 years). Eighty-five percent of the patients experienced at least a 50% reduction in the temporal migraine index and 55% reported complete elimination of temporal migraines.

Non-migraine headache

No studies were identified that evaluated surgical deactivation of trigger sites as a treatment of non-migraine headache.

Summary

The evidence on the effectiveness of surgical deactivation of trigger sites to treat migraine headache consists of 2 randomized controlled trials (RCTs) by the same research group; 1 RCT was double-blind and sham-controlled and the other was nonblinded without sham control. This is the same research group that developed the surgical procedures. In the 2 published RCTs, patients were selected for randomization based on clinical evaluation and their response to injections of botulinum toxin A. Findings of a 2012 analysis questions the necessity of using diagnostic botulinum toxin injections for patient selection; however, the efficacy of surgical deactivation of trigger sites following patient selection by clinical evaluation alone has not been evaluated in RCTs. Both trials reported statistically significantly better outcomes at 12 months in patients who received active surgery for migraine headache. In addition, several case series, but no controlled studies, have been published by other research groups.

This evidence is suggestive of a benefit from surgical deactivation, but is not sufficient to form definite conclusions. There is a need for additional sham-controlled randomized studies by other research groups to confirm the results of the 2 published RCTs. In addition, there is a need for further refinement of patient selection criteria and

evaluation of any altered selection process e.g., without the use of diagnostic botulinum toxin A injections in controlled studies. Thus, surgical deactivation of trigger sites to treat migraine headache is considered investigational.

No published studies have evaluated surgical deactivation of trigger sites as a treatment of non-migraine headache, and therefore, this is considered investigational.

Supplemental Information

Practice Guidelines and Position Statements

In 2013, the American Headache Society Board of Directors approved a list of 5 items that provide low value in headache medicine.¹⁴ This list was produced as part of the American Board of Internal Medicine Foundations Choosing Wisely Initiative. One of the 5 recommendations was, "Don't recommend surgical deactivation of migraine trigger points outside of a clinical trial." The published document states that the value of this procedure is still a research question and that large, multicenter RCTs with long-term follow-up are needed to provide accurate information on its benefits and harms.

The American Academy of Neurology evidence-based headache guidelines do not address surgical deactivation of trigger points.

U.S Preventive Services Task Force Recommendations

Surgical deactivation of headache trigger points is not a preventive service.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

References

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13. Kurlander DE, Punjabi A, Liu MT, et al. In-depth review of symptoms, triggers, and treatment of temporal migraine headaches (Site II). *Plast Reconstr Surg*. Apr 2014;133(4):897-903. PMID 24675192
14. Loder E, Weizenbaum E, Frishberg B, et al. Choosing wisely in headache medicine: the American Headache Society's list of five things physicians and patients should question. *Headache*. Nov-Dec 2013;53(10):1651-1659. PMID 24266337
15. Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 7.01.135 (August 2014).

Documentation Required for Clinical Review

- History and physical including:
 - Consultation report(s)
 - Previous treatment and response

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

IE

The following services are considered investigational and therefore not covered for any indication.

Type	Code	Description
CPT®	See Policy Guidelines	
	15824	Rhytidectomy; forehead
	15826	Rhytidectomy; glabellar frown lines
	30130	Excision inferior turbinate, partial or complete, any method
	30140	Submucous resection inferior turbinate, partial or complete, any method
	30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
	64716	Neuroplasty and/or transposition; cranial nerve (specify)

	67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
HCPC	None	
ICD-9 Procedure	None	
ICD-10 Procedure	<i>For dates of service on or after 10/01/2015</i>	
	008K0ZZ, 008K3ZZ, 008K4ZZ	Surgical, central nervous system, division, trigeminal nerve, code by approach
	00BK0ZZ, 00BK3ZZ, 00BK4ZZ	Surgical, central nervous system, excision, trigeminal nerve, code by approach
	00NK0ZZ, 00NK3ZZ, 00NK4ZZ	Surgical, central nervous system, release, trigeminal nerve, code by approach
	09BL0ZZ, 09BL3ZZ, 09BL4ZZ, 09BL7ZZ, 09BL8ZZ	Surgical, ear, nose, sinus, excision, nasal turbinate, code by approach
	09BM0ZZ, 09BM3ZZ, 09BM4ZZ	Surgical, ear, nose, sinus, excision, nasal septum, code by approach
	09TL0ZZ, 09TL4ZZ, 09TL7ZZ, 09TL8ZZ	Surgical, ear, nose, sinus, resection, nasal turbinate, code by approach
	0HQ1XZZ	Surgical, skin, repair, face, external
	0W020ZZ, 0W023ZZ, 0W024ZZ	Surgical, anatomical region, alteration, face, code by approach
ICD-9 Diagnosis	All Diagnoses	
ICD-10 Diagnosis	<i>For dates of service on or after 10/01/2015</i>	
	<i>Investigational for all relevant diagnoses</i>	
	All Diagnoses	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
09/30/2014	BCBSA Medical Policy adoption	Medical Policy Committee

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.