APPENDIX to Regional Sympathetic Blocks Policy

Prior Authorization Requirements

Clinical Evidence is required to determine **medical necessity**.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield of California / Blue Shield of California Life & Health Insurance Company (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.

Evidence Basis for the Policy

Rationale

The sympathetic nervous system (SNS) is a part of the autonomic nervous system that controls the body's involuntary activities. According to authors Day M (2008) and Boas R et al. (1998):

> The sympathetic nervous system has been implicated in neuropathic pain (NeP), vascular, and visceral pain. Sympathetic ganglia have been the target of local anesthetic block to assess the role of the SNS in transmission of pain. Despite the frequent use of minimally invasive sympathetic blocks by pain practitioners, their efficacy for providing analgesia has been sparsely reported. Many case reports and series have been published, but few placebo-controlled, blinded studies exist.

Nerve Blocks for Regional Sympathetic Block

Nerve blocks for regional sympathetic blocks (RSB) result in a temporary interruption of the conduction of impulses in nerves. This is accomplished by the injection of local anesthetic solutions. Since sympathetic fibers are the least myelineated, they are the first affected by local anesthetic.

Stellate Ganglion Blockade

A stellate ganglion blockade (SGB) is an injection of local anesthetic in the sympathetic nerve tissue of the neck. These nerves are a part of the SNS. The stellate ganglion is located at the level of the 7th cervical vertebrae. A SGB blocks the sympathetic nerves that go to the arms, and, to

some degree, the sympathetic nerves that go to the face. This may in turn reduce pain, swelling, color and sweating changes in the upper extremity and may improve mobility. It is done as a part of the treatment of RSD, sympathetic maintained pain (SMP), complex regional pain syndrome (CRPS) and Herpes Zoster involving an arm or the head and face.

Ackerman and Zhang (2006) reported on a study to examine the efficacy SGB in patients with CRPS type I of their hands. They reported on 25 subjects with a clinical diagnosis of CRPS type I of one hand as defined by the International Association for the Study of Pain (IASP) criteria, who had three SGB's performed at weekly interval. Pre- and post-SGB therapy, laser doppler fluxmetric hand perfusion studies were performed on both the normal and CRPS type I hand. A large percentage of patients achieved complete (40%) or partial (36%) relief of their symptoms. Only 6 of 25 (24%) patients showed no relief. The authors stated SGB was not a totally benign procedure, and not all patients with CRPS of the hand respond to this treatment.

Lumbar Sympathetic Block

Lumbar sympathetic nerve blocks (LSB) are a procedure used to block or decrease pain in the lower extremities caused by injury or disease of the SNS. The LSN blocks are located on either side of the lumbar spine.

Analgesic Response to Sympathetic Blockade in Complex Regional Syndrome

Complex regional pain syndrome (CRPS) is a disorder of the extremities that is characterized by pain, swelling, limited range of motion, vasomotor instability, skin changes, and patchy bone demineralization. It frequently begins following an injury, surgery, or vascular event such as a myocardial infarction or stroke.

This syndrome is defined by the IASP as:

> ...a variety of painful conditions following injury which appear regionally having a distal predominance of abnormal findings, exceeding in both magnitude and duration the expected clinical course of the inciting event and often resulting in significant impairment of motor function, and showing variable progression over time. (Stanton-Hicks, 2004).

A further defining in 2008 by the Reflex Sympathetic Dystrophy Syndrome Association (RSDSA) describes CRPS "as an injury to a nerve or soft-tissue that does not follow the normal healing pattern." Development of CRPS does not appear to depend upon the magnitude of the original injury, and the SNS seems to assume an abnormal function in CRPS. The syndrome may be divided into CRPS type I (formerly known as RSD) where there is no recognized injury to a nerve, and CRPS type II (formerly known as causalgia) where a nerve injury is identified. Psychological factors may play a role in the etiology of CRPS, and psychological treatment is often used, although there is little evidence to support this treatment. (RSDSA, 2008).

According to Parilla et al. (2008), CRPS occurs after approximately 5% of all injuries such as fractures, sprains, and trivial soft-tissue injuries, although estimates range from 1% to 15% of cases involving peripheral nerve injury and up to 30% of cases involving contusions and fractures. This syndrome affects women more than men and is thought to affect between 200,000 and 1.2 million Americans.

There seem to be differences in the presentation and response to treatment of CRPS in adults compared with children. Adults tend to have a precipitating trauma, greater incidence of CRPS in the upper versus lower extremities, and poorer response to therapy (Sherry et al., 1999; Murray et al., 2000). Psychological factors may play a role in the etiology of CRPS, and psychological treatment is often used, although there is little evidence to support this treatment. (RSDSA, 2008).

In addition to injury, CRPS can also occur as a result of various medical disorders or illnesses. The diagnostic criterion for CRPS according to Harden et al. (2007) are as follows:

- Continuing pain that is disproportionate to any inciting event
- Must report **at least one of the symptoms in the following categories**:
    - Sensory: reports of hyperesthesia
    - Vasomotor: reports of temperature asymmetry and/or skin color changes and/or skin color asymmetry
    - Sudomotor/edema: reports of edema and/or sweating changes and/or sweating asymmetry
    - Motor/trophic: reports of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin)
- Must display at least one of the signs in two or more of the following categories:
    - Sensory: evidence of hyperalgesia (to pinprick) and/or allodynia (to light touch)
    - Vasomotor: evidence of temperature asymmetry and/or skin color changes and/or asymmetry
    - Sudomotor/edema: evidence of edema and/or sweating changes and/or sweating asymmetry
    - Motor/trophic: evidence of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin)
- There is no other diagnosis that better explains the signs and symptoms

According to Cepeda et al. (2002), there was growing controversy on the value of blocking the SNS for the treatment of CRPS. The authors sought to evaluate the efficacy of sympathetic blockade with local anesthetic in these syndromes. In addition, they performed a comprehensive review of the pathophysiology and other treatments for CRPS. The authors identified only three randomized controlled trials (RCTs) that evaluated sympathetic blockade with local anesthetic, but because of differences in study design they were unable to pool the study data. The authors therefore included nonrandomized studies and case series, which allowed inclusion if local anesthetic sympathetic blockade was used in at least 10 patients. Studies were excluded if continuous infusion techniques, somatic nerve blocks, or combined sympatholytic therapies were evaluated. The pain relief classification was assessed as full, partial, or absent. Twenty-nine studies were included and 1,144 patients were evaluated. Quality of the publications was poor. Twenty-nine percent of patients had full response, 41% had partial response, and 32% had absent response. It was not possible to estimate the duration of pain relief. The authors concluded this review raises questions as to the efficacy of local anesthetic sympathetic blockade as treatment of CRPS. With the efficacy based mainly on case series, less than one third of patients obtaining

full pain relief, and absence of control groups in case series, all led to an overestimation of the treatment response that can explain the findings.

In 2008, Day M. discussed multiple sympathetic blocks, and noted that thoracic sympathetic block were not recommended due to a lack of literature to support effectiveness. He further noted that "Despite the frequent use of minimally invasive sympathetic blocks by pain practitioners, their efficacy for providing analgesia has been sparsely reported. Many case reports and series have been published, but few placebo-controlled, blinded studies exist".

In 2010, Cepeda et al. stated the efficacy of local anesthetic sympathetic blockade for CRPS was unknown. It was now conceptualized that the pathophysiology of the SNS ties together RSD and causalgia into one entity: CRPS. Therefore, blockade of the SNS is used to treat this pain syndrome. As the authors performed a review to evaluate the efficacy of sympathetic blockade with local anesthetic, they noted their evaluation revealed a scarcity of published evidence to support the use of local anesthetic sympathetic blockade as the "gold standard" for treating CRPS and stated it raised questions as to its usefulness. A systematic meta-analysis was published that had three objectives:

- To determines the likelihood of pain alleviation after sympathetic blockade with local anesthetic in the patient with CRPS
- To assess how long any benefit persists
- To evaluate the incidence of adverse effects of the procedure

The data collected and analyzed studied the number of patients who obtained at least 50% of pain relief shortly after sympathetic blockade (30 minutes to 2 hrs) and 48 hours or later. There were two small randomized double blind cross over studies found that evaluated 23 subjects. The combined results of the two trials produced a relative risk (RR) to achieve at least 50% of pain relief in 30 minutes to 2 hours after the sympathetic blockade of 1.17 (95% confidence interval [CI 0.80-1.72). Because the authors of the two studies evaluated different outcomes, it was not possible to determine the effect of the sympathetic blockade on long-term pain relief. The author concluded that this systematic review revealed the scarcity of published evidence to support the use of local anesthetic sympathetic blockade as the "gold standard" treatment for CRPS. The two randomized studies that met inclusion criteria had very small sample sizes. Therefore, no conclusion concerning the effectiveness of this procedure could be drawn. The author also concluded there is a need to conduct RCT(s) to address the value of sympathetic blockade with local anesthetic for the treatment of CRPS.

A study was performed in 2009 by Yucel and colleagues to evaluate the treatment of CRPS type I with stellate ganglion blockade. Three blockades were performed at weekly intervals in 22 patients with CRPS type I in one hand. The patients were divided into two groups depending on the time between symptom onset and treatment initiation. Group 1 and 2 patients had short and long symptom-onset-to-treatment intervals, respectively. Measuring the pain intensity, using a visual analog score (VAS), and using range of motion (ROM) for the wrist joint were assessed before and 2 weeks after treatments. They were then compared using nonparametric statistical analysis. The results of treatment produced a statistically significant difference in wrist ROM for all patients ($P < 0.0001$). Visual analog score values showed an overall decrease from 8 +/- 1 to 1 +/- 1 after treatment, and there was a significant difference in VAS value between groups 1 and 2

($P < 0.05$). The authors of this study concluded that stellate ganglion blockade successfully decreased and increased ROM of wrist joints in patients with CRPS type I. They also concluded the duration between symptom onset and therapy initiation was a major factor affecting blockade success.

In 2012, van Eijis and colleagues reported on a prospective observational study done with 49 patients with CRPS type I in one extremity only and for less than 1 year duration who had severe pain and persistent functional impairment with no response to standard treatment with medication and physical therapy. Fifteen (31%0 patients had good to moderate response when sympathetic blockade for CRPS was used. In patient groups with cold or warm type CRPS type I or in those with +/- 1.5differential increase in skin temperature after sympathetic blockade, the response rate was not different. In CRPS type I, allodynia and hypoesthesia were negative predictors for treatment success, and there were no other signs or symptoms that positively predicted treatment success. There were transient side effects such as headache, dysphagia, increased pain, backache, nausea, blurred vision, groin pain, hoarseness, and hematoma at the puncture site that were experienced by a majority of patients (84%). Major complications were not reported.

In late 2012, Neil stated “Despite many advances in our understanding of the pathophysiology of this condition, CRPS remains a challenging clinical problem." This author responded to van Eiji's report mentioned as the 2012 study above, stating there were a number of other important therapeutic options that were not considered as initial therapy. He continued on to describe pharmaceutical interventions (e.g., prednisolone), tricyclic antidepressants, alone or in combination with anticonvulsants, which were not used in this study. Neil stated:

> The use of short courses of steroids and the combinations of tricyclic antidepressants and anticonvulsants for a period of not less than 4 weeks at the maximum tolerated dose should be recommended in addition to physical therapy as standard initial management, and that sympathetic blockade should be reserved for all but the most refractory cases of CRPS.
>
> The Washington State Department of Labor and Industries (1997) outlined conservative care guidelines that advocated:
>
> - Less than or equal to 5 sympathetic nerve blocks followed immediately by physical therapy (PT)/occupational therapy (OT) within the first 6 weeks.
> - Thereafter, psychiatric or psychological consultation should be considered, if the disability was extended beyond 3 months and PT/OT continued, based on documented response in the first 6 weeks.
> - If previous blocks were successful, sympathetic blocks could be continued every other week for </= 12 weeks.
> - The protocol for PT/OT recommended active exercise programs featuring progressive weight bearing for affected lower extremities and progressive improvement of grip strength, pinch strength, and ROM for involved upper extremities in combination with a desensitization program.

In 2008, Oerlemans and colleagues provided preliminary evidence that rehabilitation therapy benefited adults who had CRPS. In adults, an RCT found that, compared with medical therapy

and guidance from a social worker, PT provided a statistically significant improvement in a multi-component measure of impairment. Based on criteria provided by the investigators, this improvement reached the minimum level necessary to qualify as clinically significant. A shortcoming of the study was that it did not involve any follow-up after the post-treatment assessment to evaluate the durability of improvements provided by PT. Moreover, it was difficult to compare outcomes of the available studies due to differences in treatment protocols. Authors stated additional controlled studies are needed to confirm that rehabilitation therapy provides clinically significant long-term benefits for adults and children who have CRPS.

Although the interventional therapies in CRPS (such as nerve blockade, sympathetic block, spinal cord and peripheral nerve stimulation, implantable spinal medication pumps, and chemical and surgical sympathectomy) may offer more rapid response, yet it is still controversial with unpredictable outcome (Hsu Es. 2009).

Menon & Swanepoel (2010) state “There is no consensus about the optimum technique, interval between blocks, and duration of treatment” for sympathetic blocks.

Several clinical trials were found that have been completed but without posted study results. Others were terminated or are currently recruiting for participants.

Summary

By and large, RSBs are considered acceptable medical practice and may be medically necessary for treatment within a specific subset of patients who have not responded to standard therapies, or for whom standard therapies are contraindicated. Even with their poor evidence base, these blocks are still commonly used clinically. Further studies are needed, and in the meantime, patients with little or no relief from conservative management will probably continue to have sympathetic blocks to try to achieve symptom control. The balance of benefits and risks in each case is therefore crucial, if the use of these techniques is to be justified.

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.

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.

Type	Number	Description
CPT	64510	Injection, anesthetic agent; stellate ganglion (cervical sympathetic)
	64520	Injection, anesthetic agent; lumbar or thoracic (paravertebral sympathetic)
HCPC	None	
ICD9 Procedure	None	
ICD9 Diagnosis	All Diagnoses	
Place of Service	All Places of Service	

Tables

N/A

Definitions

N/A

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

- Epidural Steroid Injections
- Facet Joint Injections and Facet Joint Nerve Blocks
- Sacroiliac Joint Injections

Key / Related Searchable Words

- Regional Sympathetic Block
- Stellate ganglion block

- Lumbar sympathetic chain block
- Complex regional pain syndrome

References

- Ackerman WE, Zhang JM. Efficacy of stellate ganglion blockade for the management of type 1 complex regional pain syndrome. South Med J. 2006 Oct; 99(10):1084-8.
- Boas R. Sympathetic nerve blocks: In search of a role. Reg Anesth Pain Med. 1998; 23:292-305.
- Bruehl S, Harden RN, Galer BS et al. External validation of IASP diagnostic criteria for complex regional pain syndrome and proposed research diagnostic criteria. Pain. 1999; 81:147-54.
- Cepeda MS et al. Local anaesthetic sympathetic blockade for complex regional pain syndrome. Cochrane Database of Systematic Reviews 2005, Issue 4. Art. No.: CD004598. Published online January 20, 2010. Retrieved February 12, 2013 from http://summaries.cochrane.org/CD004598/local-anesthetic-sympathetic-blockade-for-complex-regional-pain-syndrome.
- Cepeda MS, Lau J, Carr DB. Defining the therapeutic role of local anesthetic sympathetic blockade in complex regional pain syndrome: A narrative and systematic review. Clin J Pain. 2002; 18:216-33.
- Day M. Sympathetic blocks: The evidence. Pain Pract. 2008;(8):98-109.
- Day, M. Sympathetic blocks: The evidence. Pain Pract. 2008; 8:98-109.
- Harden RN, Bruehl S, Stanton-Hicks M et al. Proposed new diagnostic criteria for complex regional pain syndrome. Pain Med. 2007 May-Jun; 8(4):326-31.
- Hsu Es. Practical management of complex regional pain syndrome. Am J Ther. 2009 Mar-Apr; 16(2):147-54.
- Menon R, Swanepoel A. Sympathetic blocks. Continuing Education in Anaesthesia, Critical Care & Pain. 2010. Retrieved June 14, 2013 from http://ceaccp.oxfordjournals.org.
- Murray et al. Morbidity in reflex sympathetic dystrophy. Arch Dis Child. 2000; 82(3):231-233.
- Neil MJ. Predictors of analgesic response to sympathetic blockade in complex regional syndrome type 1. Anesthesiology. 2012 Aug; 117(2):427-8.
- Oerlemans et al. Adjunct physical therapy versus occupational therapy in patients with reflex sympathetic dystrophy/complex regional pain syndrome type I. Arch Phys Med Rehabil. 2000; 81(1):49-56.
- Parillo SJ. Complex Regional Pain Syndrome. eMedicine. 2008. Retrieved February 12, 2013 from http://www.emedicine.com/emerg/topic497.htm.
- Reflex Sympathetic Dystrophy Syndrome Association (RSDSA). Complex Regional Pain Syndrome: Treatment Guidelines. 2008c. Retrieved February 12, 2013 from http://www.rsds.org/3/clinical_guidelines/index.html.

- Reflex Sympathetic Dystrophy Syndrome Association (RSDSA). What is CRPS? 2008. Retrieved on February 12, 2013 from http://ceaccp.oxfordjournals.org/content/early/2010/04/25/bjaceaccp.mkq012.full.
- Sherry et al. Short- and long-term outcomes of children with complex regional pain syndrome type I treated with exercise therapy. Clin J Pain. 1999; 15(3):218-223.
- van Eijis et al. Predictors of pain relieving response to sympathetic blockade in complex regional syndrome. Anesthesiology. 2012; 116:113-21.
- Washington State Department of Labor and Industries (WSDLI). Complex regional pain syndrome. Medical Treatment Guidelines. June 1997; Provider Bulletin 97-05. Retrieved February12, 2013 from http://www.lni.wa.gov/claimsins/files/omd/medtreat/complexregionalpain.pdf.
- Yucel et al. Complex regional pain syndrome type I: Efficacy of stellate ganglion blockade. J Orthop Traumatol. 2009 Dec; 10(4):179-83.

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
3/5/2012	New policy	Medical Policy Committee
5/8/2012	Administrative Update	Administrative Review
1/11/2013	Added Note to Position Statement for review clarification purposes	Medical Policy Committee
6/28/2013	Policy revision with position change	Medical Policy Committee

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.

Click here to view the policy statement for this policy

An Independent Member of the Blue Shield Association