



Specialty Independent Review Organization

**Date notice sent to all parties:** 5/1/2016

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

The item in dispute is the prospective medical necessity of 3 stellate ganglion nerve blocks.

**A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:**

The reviewer is a Medical Doctor who is board certified in Anesthesiology.

**REVIEW OUTCOME:**

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

The reviewer agrees with the previous adverse determination regarding the prospective medical necessity of 3 stellate ganglion nerve blocks.

A copy of the ODG was not provided by the Carrier or URA for this review.

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The patient is a male who sustained an injury on XX/XX/XX. He was injured when a 600-lb piece of equipment hit his head. He had multiple head and maxillofacial surgeries and extensive dental procedures. On XX/XX/XX, peer review modified the request for acupuncture 8 visits to allow for a trial of 4 acupuncture treatments. Patient reported great relief from acupuncture treatment. He has increased pain associated with recent dental work. Reduction of fentanyl dose from 25 mcg/hr to 12mcg/hr was discussed. Patient was functionally stable and working several days a week with minimal discomfort. Per clinical note on XX/XX/XX, the patient reported acupuncture provided excellent pain relief for 7-8 hours. He felt his pain was aggravated now that he had to undergo extensive dental work recently. He was currently using fentanyl 25mcg/hr and working 26 hours per week.

The patient was examined on XX/XX/XX. It was agreed during the peer to peer discussion to discontinue fentanyl and add an analgesic adjuvant such as nortriptyline to obtain additional pain relief and to use short acting analgesics for breakthrough pain. Plan was to start amitriptyline 10mg at night, schedule the patient for a left stellate ganglion block and transition the patient from fentanyl patch to hydrocodone. It was hoped that the stellate ganglion block would aid in pain control to transition him from fentanyl patch to hydrocodone.

**ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:**

Based on the clinical information submitted for this review, this request is non-certified. There was no documentation of any evidence of temperature or color change, pseudomotor/edema or hyperalgesia, allodynia, trophic changes. The Budapest (Harden) criteria have not been fulfilled. Therefore, this request is not medically necessary.

ODG, Pain Chapter

Recommend using a combination of criteria as per the revised Budapest (Harden) criteria as indicated below to make this diagnosis. There are no objective gold-standard diagnostic criteria for CRPS I or II. The diagnosis is based on what are predominately subjective criteria which are shared by many other diseases (see Differential diagnosis below). Current diagnostic criteria specifically indicate that there can be no other diagnosis that better explains signs and symptoms. The importance of establishing a correct diagnosis and to prevent potentially harmful and/ or unwarranted treatment cannot be emphasized enough.

Pathophysiology: Multiple hypotheses have been promoted to explain both CRPS I and II. These include peripheral mechanisms that are inflammatory, altered cutaneous innervation after injury, peripheral sensitization, altered sympathetic and catecholaminergic function, altered somatosensory representation in the brain, genetic factors, central mechanisms, and psychophysiological interactions. Lab findings have included signs of increased neurogenic inflammation, small fiber neuropathy, tissue hypoxia and altered immune response. Most researchers feel that the interaction between these multiple pathways is what explains the heterogeneity of presentation and course. (Marinus, 2011) (Bruehl, 2010) The associations of non-dermatomal patterns of pain, unusual movement disorders and somatovisceral dysfunction have been particularly difficult to explain. In addition, the objective physical signs of CRPS, including imaging, can be created with disuse and or physical manipulation. (Cooper, 2013) (Bruehl, 2010) (Harden, 2013) (Goebel, 2012) (Rodriguez-Moreno, 1990)

The Budapest (Harden) Criteria represent a revision of the above IASP Criteria. There are two versions of these proposed diagnostic criteria. A diagnostic version was developed to maximize sensitivity (identify true positive cases) with

adequate specificity (i.e. avoiding a false positive diagnosis). A research version was developed to more equally balance sensitivity and specificity. The diagnostic criteria are the following:

- (1) Continuing pain, which is disproportionate to any inciting event;
  - (2) Must report at least one symptom in three of the four following categories: (a) Sensory: Reports of hyperesthesia and/or allodynia; (b) Vasomotor: Reports of temperature asymmetry and/or skin color changes and/or skin color asymmetry; (c) Sudomotor/Edema: Reports of edema and/or sweating changes and/or sweating asymmetry; (d) Motor/Trophic: Reports of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin);
  - (3) Must display at least one sign at time of evaluation in two or more of the following categories: (a) Sensory: Evidence of hyperalgesia (to pinprick) and/or allodynia (to light touch and/or temperature sensation and/or deep somatic pressure and/or joint movement); (b) Vasomotor: Evidence of temperature asymmetry ( $>1^{\circ}\text{C}$ ) and/or skin color changes and/or asymmetry; (c) Sudomotor/Edema: Evidence of edema and/or sweating changes and/or sweating asymmetry; (d) Motor/Trophic: Evidence of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin);
  - (4) There is no other diagnosis that better explains the signs and symptoms.
- (Harden, 2007) (Harden, 2010) This diagnostic version produces a sensitivity of 85% and specificity of 69%. The research version requires reporting of at least one symptom in each of the four categories (vs. in three of the four in the diagnostic version). This provides a sensitivity of 70% and specificity of 96%. (Harden, 2013)

Recommendations (based on consensus guidelines) for use of sympathetic blocks (diagnostic block recommendations are included here, as well as in CRPS, diagnostic tests):

- (1) There should be evidence that all other diagnoses have been ruled out before consideration of use.
- (2) There should be evidence that the Budapest (Harden) criteria have been evaluated for and fulfilled.
- (3) If a sympathetic block is utilized for diagnosis, there should be evidence that this block fulfills criteria for success including that skin temperature after the block shows sustained increase ( $\geq 1.5^{\circ}\text{C}$  and/or an increase in temperature to  $> 34^{\circ}\text{C}$ ) without evidence of thermal or tactile sensory block. Documentation of motor and/or sensory block should occur. This is particularly important in the diagnostic phase to avoid overestimation of the sympathetic component of pain. A Horner's sign should be documented for upper extremity blocks. The use of sedation with the block can influence results, and this should be documented if utilized. (Krumova, 2011) (Schurmann, 2001)
- (4) Therapeutic use of sympathetic blocks is only recommended in cases that have positive response to diagnostic blocks and diagnostic criteria are fulfilled (See #1-3). These blocks are only recommended if there is evidence of lack of

response to conservative treatment including pharmacologic therapy and physical rehabilitation.

(5) In the initial therapeutic phase, maximum sustained relief is generally obtained after 3 to 6 blocks. These blocks are generally given in fairly quick succession in the first two weeks of treatment with tapering to once a week. Continuing treatment longer than 2 to 3 weeks is unusual.

(6) In the therapeutic phase repeat blocks should only be undertaken if there is evidence of increased range of motion, pain and medication use reduction, and increased tolerance of activity and touch (decreased allodynia) is documented to permit participation in physical therapy/ occupational therapy. Sympathetic blocks are not a stand-alone treatment.

(7) There should be evidence that physical or occupational therapy is incorporated with the duration of symptom relief of the block during the therapeutic phase.

(8) In acute exacerbations of patients who have documented evidence of sympathetically mediated pain (see #1-3), 1 to 3 blocks may be required for treatment.

(9) A formal test of the therapeutic blocks should be documented (preferably using skin temperature).

(Burton, 2006) (Stanton-Hicks, 2004) (Stanton-Hicks, 2006) (International Research Foundation for RSD/CRPS, 2003) (Colorado, 2006) (Washington, 2002) (Rho, 2002) (Perez, 2010) (van Eijs, 2011)

Recommend hierarchy of options as indicated below. The goal is to improve function. There are no evidence-based treatment guidelines, but several groups have begun to organize treatment algorithms that are consensus based. There is currently no intervention for CRPS that can be considered to be supported by strong evidence of efficacy. (Ribbers, 2003) (Stanton-Hicks, 2006) (O'Connell, 2013) Interdisciplinary management is recommended emphasizing functional restoration. (Harden, 2013) (Singh, 2004) (Albazaz, 2008) (Hsu, 2009)

1. Rehabilitation: (a) Early stages: Build a therapeutic alliance. Analgesia, encouragement and education are key. Physical modalities include desensitization, isometric exercises, resisted range of motion, and stress loading. If not applied appropriately, PT may temporarily increase symptoms, particularly if too aggressive. (b) Next steps: Increase flexibility with introduction of gentle active ROM and stretching (to treat accompanying myofascial pain syndrome). Other interventions to enhance participation in rehabilitation may include muscle relaxants, trigger point injections and electrical stimulation (based on anecdotal evidence). Edema control may also be required (elevation, retrograde sympathetic blocks, diuretics and adrenoceptor blockers when sympathetically maintained pain-SMP is present). (c) Continued steps: Continue active ROM, stress loading, scrubbing techniques, isotonic strengthening, general aerobic conditioning, and postural normalization. (d) Final steps: Normalization of use, assessment of ergonomics, and posture and modifications at home and work.

2. Psychological treatment: Focused on improved quality of life, development of pain coping skills, cognitive-behavioral therapy, and improving facilitation of other modalities. (a) Early stages: Education. (b) Next steps: Clinical psychological

assessment, after 6 to 8 weeks, identification of stressors, and identification of comorbid Axis I psychiatric disorders (depression, anxiety, panic and post-traumatic stress).

### 3. Pain management:

Pharmacological treatment: See CRPS, medications.

Invasive treatment: The role of sympathetic blocks is largely empirical with lack of solid evidence. See CRPS, sympathetic blocks, (therapeutic) for more specific information and criteria for use of sympathetic treatment.

Local anesthetic sympathetic blocks: Recommended for limited, select cases, primarily for diagnosis of sympathetically mediated pain and therapeutically as an adjunct to facilitate physical therapy/ functional restoration. When used for the latter the procedure is not considered a stand-alone procedure. The role of sympathetic blocks for treatment of CRPS is largely empirical (with a general lack of evidence-based research for support) but can be clinically important in individual cases in which the procedure ameliorates pain and improves function, allowing for a less painful “window of opportunity” for rehabilitation techniques. (Harden, 2013)

Sympathectomy: Not recommended. See CRPS, sympathectomy.

IV regional anesthesia: Not recommended due to lack of evidence for use. See CRPS, sympathetic blocks, (therapeutic); Intravenous regional sympathetic blocks (for RSD/CRPS).

Epidural infusions for sympathetic blockade: Not recommended due to lack of evidence for use and high risk of complications including infection. There is one randomized controlled trial that reported improvement. A study that included both randomized and open label design (26 patients) using clonidine showed pain relief, but the authors considered this experimental and the study has not been repeated. Infections occurred in 6/19 patients who ultimately received the treatment. (Rauck, 1993)

Brachial plexus blocks: Not recommended due to the lack of evidence for use and risk of complications including infection, intravascular injection, pneumothorax, and phrenic nerve paralysis. (Harden, 2013) (Tran, 2010)

Intrathecal drugs: Opioids are not recommended. Baclofen may play a limited, end-stage role for treatment for patients with dystonia, the area which the limited research addresses. The first study was conducted in 7 patients using IASP criteria. Six of these received a pump. Greater effect was found in the arms than legs. When followed for a year, the largest improvement was noted in the first three months with stabilization around a one year period. Lack of responsiveness to intrathecal baclofen declined in 30% of patients once delivery was switched from external to implantable treatment. A large number of adverse events were noted with the most common being post-dural headache. In this second study the authors indicated that to enhance therapeutic potential, methods to improve patient selection and catheter-pump integrity were warranted. Increasing the infusion rate did not result in improvement of dystonia. The authors also note that significant improvement in global intense pain, sharp pain, dull pain and deep pain occurred in the first six months of this open design, but after this period the

scores leveled despite further improvement of dystonia and continued ITB dose escalation. (van der Plas, 2013) (van Rijn, 2009)

Spinal Cord Stimulator: See CRPS, spinal cord stimulators.

See also CRPS, pathophysiology (clinical presentation & diagnostic criteria); CRPS, medications; CRPS, sympathetic blocks (therapeutic); Intravenous regional sympathetic blocks (for RSD/CRPS); & Sympathetically maintained pain (SMP).

**A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:**

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
  
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
  
- INTERQUAL CRITERIA**
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
  
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
  
- MILLIMAN CARE GUIDELINES**
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
  
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
  
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
  
- TEXAS TACADA GUIDELINES**
  
- TMF SCREENING CRITERIA MANUAL**
  
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
  
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**