The DYLL REVIEW
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25 Highland Park Village #100-177 Dallas TX 75205
Phone: 888-950-4333 Fax: 888-9504-4443

Notice of Independent Review Decision

December 19, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Cervical ESI under Fluoroscopy with IV sedation

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

The physician performing this review is Board Certified, American Board of Physical Medicine & Rehabilitation. The physician is certified in pain management. The physician has a private practice of Physical Medicine & Rehabilitation, Electro Diagnostic Medicine & Pain Management. The physician is a member of the Texas Medical Association and the Houston Physical Medicine and Rehabilitation Society. The physician is licensed in Texas and Michigan and has been in practice for over 25 years.

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)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

Upon independent Review the physician finds that the previous adverse determination should be Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

Records Received: 19 page fax 12/02/13 Department of Insurance IRO request, 82 pages of documents received via fax on 12/02/13 URA response to disputed services including administrative and medical. 44 pages of documents received via USPS on 12/09/13 Provider response to disputed services including administrative and medical. Dates of documents range from 1/24/12 to 12/02/13.

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PATIENT CLINICAL HISTORY [SUMMARY]:

This is a woman with pain in shoulder and neck following injury on xx/xx/xx. She was diagnosed as having CRPS based upon clinical criteria. The electrodiagnostic studies from 3/22/12 and 10/4/12 showed no evidence of any cervical radiculopathy. I did not see a cervical MRI. She had transient relief of her symptoms with two right stellate blocks done on 7/23/13 and 8/13/13. described her symptoms as worsening and reports that the ODG justifies the use of cervical ESIs in his notes on 9/19/13 and 10/15/13. Other notes describe his frustration with the Workers Comp system.

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

I am unable to certify the role for ESI injections for the treatment of CRPS. The reasons follow.

First, the ODG discusses the role of cervical ESIs in the cervical section as being limited to cervical radiculopathy with evidence of both clinical and radiological findings. "Recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy…"
Second, I approached the ESIs in the pain section and found much the same. Most of the ODG sections on CRPS discussed sympathetic blocks and the diagnostic criteria. The following is the section labeled treatment where no treatment was considered to have strong evidence of efficacy (emphasis mine). There are discussion of the role of different sympathetic treatment options. There is no support for the role of epidural infusions, let alone epidural blocks. There is a discussion for intrathecal treatments, but this is not the same as an epidural block. This was not described in the medication section either.

Cervical Epidural

Recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy). See specific criteria for use below. [NOTE: This treatment for Low back & Neck pain is primarily covered in those respective chapters.] Most current guidelines recommend no more than 2 ESI injections. This is in contradiction to previous generally cited recommendations for a "series of three" ESIs. These early recommendations were primarily based on anecdotal evidence. Research has now shown that, on average, less than two injections are required for a successful ESI outcome. Current recommendations suggest a second epidural injection if partial success is produced with the first injection, and a third ESI is rarely recommended. Epidural steroid injection can offer short term pain relief and use should be in conjunction with other rehab efforts, including continuing a home exercise program. There is little information on improved function. See the Low Back Chapter for more information and references. The American Academy of Neurology recently concluded that epidural steroid injections may lead to an improvement in radicular lumbosacral pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months, and there is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat radicular cervical pain. (Armon, 2007) See also Epidural steroid injections, "series of three". Also see the Neck and Upper Back Chapter.
Sedation: There is no evidence-based literature to make a firm recommendation as to sedation during an ESI. The use of sedation introduces some potential diagnostic and safety issues, making unnecessary use less

than ideal. A major concern is that sedation may result in the inability of the patient to experience the expected pain and paresthesias associated with spinal cord irritation. This is of particular concern in the cervical region. (Hodges 1999) Routine use is not recommended except for patients with anxiety. The least amount of sedation for the shortest duration of effect is recommended. The general agent recommended is a benzodiazepine. (Trentman 2008) (Kim 2007) (Cuccuzzella 2006) While sedation is not recommended for facet injections (especially with opioids) because it may alter the anesthetic diagnostic response, sedation is not generally necessary for an ESI but is not contraindicated. As far as monitored anesthesia care (MAC) administered by someone besides the surgeon, there should be evidence of a pre-anesthetic exam and evaluation, prescription of anesthesia care, completion of the record, administration of medication and provision of post-op care. Supervision services provided by the operating physician are considered part of the surgical service provided.

Criteria for the use of Epidural steroid injections:
Note: The purpose of ESI is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit.
1) Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing.
2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants).
3) Injections should be performed using fluoroscopy (live x-ray) for guidance.
4) If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at an interval of at least one to two weeks between injections.
5) No more than two nerve root levels should be injected using transforaminal blocks.
6) No more than one interlaminar level should be injected at one session.
7) In the therapeutic phase, repeat blocks should be based on continued objective documented pain and functional improvement, including at least 50% pain relief with associated reduction of medication use for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year. (Manchikanti, 2003) (CMS, 2004) (Boswell, 2007)
8) Current research does not support a “series-of-three” injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections.
9) Epidural steroid injection is not to be performed on the same day as trigger point injection, sacroiliac joint injection, facet joint injection or medial branch block.

CRPS, treatment

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).

CRPS Medications

Recommended only as indicated below. Most medications have limited effectiveness, and recommendations are primarily based on extrapolation from neuropathic pain medication guidelines. A reason given for the paucity of medication studies is the absence of a gold-standard diagnostic test for CRPS and lack of uniformly accepted diagnostic criteria. (Ribbers, 2003) (Quisel2, 2005) (Harden, 2013)

1. Regional inflammatory reaction: Commonly used drugs are NSAIDS, corticosteroids and free-radical scavengers. There is some evidence of efficacy for topical DMSO cream, IV bisphosphonates and limited courses of oral corticosteroids. Corticosteroids are most effective earlier in the condition when positive response is obtained with sympathetic blocks. NSAIDs are recommended but no trials have shown effectiveness in CRPS-I, and they are recommended primarily in early or very late stages. (Stanton-Hicks, 2004) (Sharma, 2006) Because long-term controlled studies have not been conducted, DMSO should be considered investigational and used only after other therapies have failed. (FDA, 2010)

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2. Stimulus-independent pain: The use of antidepressants (primarily tricyclics and SNRIs), anticonvulsants (with the most support for gabapentin), and opioids has been primarily extrapolated based on use for other neuropathic pain disorders. There are no long term studies demonstrating efficacy of opioids as treatment for CRPS. Opioids are a second- to third- line choice for patients failing other pharmacologic interventions with the understanding that long-term use can actually worsen allodynia and/or hyperalgesia. See Antidepressants for neuropathic pain; Anticonvulsants for chronic pain; & Opioids for neuropathic pain. Current literature does not support the use of clonidine. (Hsu, 2009) (Harden, 2013)
3. Stimulus-evoked pain: treatment is aimed at central sensitization. With NMDA receptor antagonists (ketamine and amantadine) convincing controlled trials are lacking, and these drugs are recognized for their side effects. See Ketamine.
4. Sympathetically maintained pain (SMP): See IV regional sympathetic blocks (for RSD/CRPS); CRPS, sympathetic block (therapeutic); CRPS, treatment.
5. Treatment of bone resorption and resultant pain with bisphosphonate-type compounds and calcitonin. Bisphosphonates include alendronate, ibandronate, risedronate, zoledronate, etidronate, and pamidronate. There is no research on the newer longer-lasting drugs that are administered by periodic IV infusion (ibandronate, zoledronate and pamidronate). Significant improvement has been found in limited studies with intravenous alendronate. Alendronate (Fosamax®) given in oral doses of 40 mg a day (over an 8 week period) produced improvements in pain, pressure tolerance and joint mobility. There has also been evidence of improvement of pain with pamidronate. Osteopenia was not an outcome. (Manicourt, 2004) Mixed results have been found with intranasal calcitonin (Miacalcin®). (Sahin, 2005) (Appelboom, 2002) (Rowbathan, 2006) (Sharma, 2006) (Perez, 2001) The mechanism of action of these drugs is uncertain.
6. Treatment of dystonia: Oral baclofen is a first-line option. Benzodiazepines and long-term use of muscle relaxants such as cyclobenzaprine are not recommended. (Harden, 2013)
7. Treatment considered experimental and not recommended: IVIG, Sildenafil

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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)