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NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:

Mar/19/2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Thoracic epidural steroid injection

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

MD, Board Certified in Physical Medicine and Rehabilitation
Subspecialty Board Certified in Pain Management

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)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Adverse Determination Letters 1/12/10, 2/2/10, 2/3/10

Neurosurgical Associates 1/7/10, 2/6/09, 2/26/09

12/7/09

Heart Institute 12/7/09

M.D. 12/7/09, 1/8/09, 12/11/08, 10/30/08, 9/18/08,

9/4/08, 8/14/08, 8/7/08, 5/22/08, 5/12/08, 4/28/08, 3/31/08, 3/6/08,

3/17/08, 1/8/10

Memorial Hospital 2/4/09, 7/22/08, 5/28/08, 5/7/08,

5/2/08, 3/28/08

M.D. 12/22/08, 12/9/08

Surgery Center 12/19/08

Ph.D. 10/16/08

1/12/10, 2/3/10

Imaging Center 1/9/08

D.C. 1/25/08, 1/23/08

ODG Guidelines, Neck and Upper Back

PATIENT CLINICAL HISTORY SUMMARY

This is a man injured on xx/xx/xx. He subsequently had mid and lower back pain. He underwent a laminectomy followed by an anterior posterior fusion at L4/5 in 2007. He had

persistent pain. A hardware block provided relief. The records describe an MRI in 2006 showing disc bulges at T5-T10. Dr. wrote on 3/6/08 that the "Original thoracic MR scan showed some multi-level disk bulging, but a thoracic MR scan ... showed nothing of significance." A CT myelogram in 2008 showed possible disc bulges with degenerative changes at T8/9. The records have a note of a small disc protrusion at T8/9 in the 5/12/08 note. The man underwent an evaluation of chest pain and mid back pain. Dr. inserted a lumbar stimulator on 12/9/08.

Dr. wrote "He has undergone some injections in the past at the T8-9 interspace." There was a negative cardiac workup and the pain was felt to be arising in his back. A trial of a thoracic epidural stimulator was performed in 1/09. He then underwent removal of the hardware at the fusion site on 2/4/09. The report included description of the placement of a Medtronic thoracic epidural stimulator from T2-4 at the same time as the hardware removal.

Dr. noted that this man had an excellent result of a left T8/9 ESI on 7/22/08, but the pain had returned fully by 8/7/08 according to the exam notes. The provider could not understand why the repeat ESI was denied. He wrote on 11/12/09 "He has pain in the thoracic and lumbar spine but no radicular pain."

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

According to the records submitted for review, this request is for a thoracic ESI for additional pain control. The cervical thoracic component of the ODG states thoracic ESI is justified as a treatment for radicular pain, and not mechanical back pain. Yet, Dr. stated very clearly that this is not radicular pain in exam note dated 11/12/09. The cervical thoracic region (combined in the ODG) requires radiological and electrodiagnostic findings. The MRI reportedly did not show this. The CT scan was suggestive of a disc bulge. The lumbar section requires reliance on the AMA Guides for the evidence of a radiculopathy. The prior ESI served as the analysis for the pain generator. The ODG requires that the first ESI provide at least 50% relief for 6-8 weeks. Here, Dr. noted that the 7/22/08 injection was no longer providing relief on the 8/7/08 note. This is 16 days, far less than the 6-8 weeks required by ODG. The records indicate the patient has pain, but no radiculopathy, possible abnormal CT scan, and a short response to a prior ESI. Based upon these medical records, there is no evidence to support the role of a repeat thoracic ESI. The reviewer finds that medical necessity does not exist at this time for thoracic epidural steroid injection.

Epidural steroid injection (ESI)

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. In a recent Cochrane review, there was one study that reported improvement in pain and function at four weeks and also one year in individuals with chronic neck pain with radiation. (Peloso-Cochrane, 2006) (Peloso, 2005) Other reviews have reported moderate short-term and long-term evidence of success in managing cervical radiculopathy with interlaminar ESIs. (Stav, 1993) (Castagnera, 1994) Some have also reported moderate evidence of management of cervical nerve root pain using a transforaminal approach. (Bush, 1996) (Cyteval, 2004) A recent retrospective review of interlaminar cervical ESIs found that approximately two-thirds of patients with symptomatic cervical radiculopathy from disc herniation were able to avoid surgery for up to 1 year with treatment. Success rate was improved with earlier injection (< 100 days from diagnosis). (Lin, 2006) There have been recent case reports of cerebellar infarct and brainstem herniation as well as spinal cord infarction after cervical transforaminal injection. (Beckman, 2006) (Ludwig, 2005) Quadriplegia with a cervical ESI at C6-7 has also been noted (Bose, 2005) and the American Society of Anesthesiologists Closed Claims Project database revealed 9 deaths or cases of brain injury after cervical ESI (1970-1999). (Fitzgibbon, 2004) These reports were in contrast to a retrospective review of 1,036 injections that showed that there were no catastrophic complications with the procedure. (Ma, 2005) 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) There is evidence for short-term symptomatic improvement of radicular symptoms with epidural or selective root injections with corticosteroids, but these treatments did not appear to decrease the rate of open surgery. (Haldeman, 2008) (Benyamin, 2009) See the Low Back Chapter for more information and references

Criteria for the use of Epidural steroid injections, therapeutic

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 only be offered if there is at least 50% pain relief for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year
- (8) Repeat injections should be based on continued objective documented pain and function response
- (9) 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
- (10) It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or stellate ganglion blocks or sympathetic blocks or trigger point injections as this may lead to improper diagnosis or unnecessary treatment
- (11) Cervical and lumbar epidural steroid injection should not be performed on the same day

Criteria for the use of Epidural steroid injections, diagnostic

To determine the level of radicular pain, in cases where diagnostic imaging is ambiguous, including the examples below:

- (1) To help to evaluate a pain generator when physical signs and symptoms differ from that found on imaging studies
- (2) To help to determine pain generators when there is evidence of multi-level nerve root compression

(3) To help to determine pain generators when clinical findings are suggestive of radiculopathy (e.g. dermatomal distribution) but imaging studies are inconclusive;

Epidural steroid injections (ESIs), therapeutic (lumbar)

Recommended as a possible option for short-term treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy) with use in conjunction with active rehab efforts. See specific criteria for use below. Radiculopathy symptoms are generally due to herniated nucleus pulposus or spinal stenosis, although ESIs have not been found to be as beneficial a treatment for the latter condition

Short-term symptoms: The American Academy of Neurology recently concluded that epidural steroid injections may lead to an improvement in radicular 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. (Armon, 2007) 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 or return to work. There is no high-level evidence to support the use of epidural injections of steroids, local anesthetics, and/or opioids as a treatment for acute low back pain without radiculopathy. (Benzon, 1986) (ISIS, 1999) (DePalma, 2005) (Molloy, 2005) (Wilson-MacDonald, 2005) This recent RCT concluded that both ESIs and PT seem to be effective for lumbar spinal stenosis for up to 6 months. Both ESI and PT groups demonstrated significant improvement in pain and functional parameters compared to control and no significant difference was noted between the 2 treatment groups at 6 months, but the ESI group was significantly more improved at the 2nd week. (Koc, 2009)

Use for chronic pain: Chronic duration of symptoms (> 6 months) has also been found to decrease success rates with a threefold decrease found in patients with symptom duration > 24 months. The ideal time of either when to initiate treatment or when treatment is no longer thought to be effective has not been determined. (Hopwood, 1993) (Cyteval, 2006) Indications for repeating ESIs in patients with chronic pain at a level previously injected (> 24 months) include a symptom-free interval or indication of a new clinical presentation at the level

Transforaminal approach: Some groups suggest that there may be a preference for a transforaminal approach as the technique allows for delivery of medication at the target tissue site, and an advantage for transforaminal injections in herniated nucleus pulposus over translaminar or caudal injections has been suggested in the best available studies. (Riew, 2000) (Vad, 2002) (Young, 2007) This approach may be particularly helpful in patients with large disc herniations, foraminal stenosis, and lateral disc herniations. (Colorado, 2001) (ICSI, 2004) (McLain, 2005) (Wilson-MacDonald, 2005)

Fluoroscopic guidance: Fluoroscopic guidance with use of contrast is recommended for all approaches as needle misplacement may be a cause of treatment failure. (Manchikanti, 1999) (Colorado, 2001) (ICSI, 2004) (Molloy, 2005) (Young, 2007)

Factors that decrease success: Decreased success rates have been found in patients who are unemployed due to pain, who smoke, have had previous back surgery, have pain that is not decreased by medication, and/or evidence of substance abuse, disability or litigation. (Jamison, 1991) (Abram, 1999) Research reporting effectiveness of ESIs in the past has been contradictory, but these discrepancies are felt to have been, in part, secondary to numerous methodological flaws in the early studies, including the lack of imaging and contrast administration. Success rates also may depend on the technical skill of the interventionalist. (Carette, 1997) (Bigos, 1999) (Rozenberg, 1999) (Botwin, 2002) (Manchikanti, 2003) (CMS, 2004) (Delpont, 2004) (Khot, 2004) (Buttermann, 2004) (Buttermann2, 2004) (Samanta, 2004) (Cigna, 2004) (Benzon, 2005) (Dashfield, 2005) (Arden, 2005) (Price, 2005) (Resnick, 2005) (Abdi, 2007) (Boswell, 2007) (Buenaventura, 2009) Also see Epidural steroid injections, "series of three" and Epidural steroid injections,

diagnostic. ESIs may be helpful with radicular symptoms not responsive to 2 to 6 weeks of conservative therapy. (Kinkade, 2007) Epidural steroid injections are an option for short-term pain relief of persistent radiculopathy, although not for nonspecific low back pain or spinal stenosis. (Chou, 2008) As noted above, injections are recommended if they can facilitate a return to functionality (via activity & exercise). If post-injection physical therapy visits are required for instruction in these active self-performed exercise programs, these visits should be included within the overall recommendations under Physical therapy, or at least not require more than 2 additional visits to reinforce the home exercise program

With discectomy: Epidural steroid administration during lumbar discectomy may reduce early neurologic impairment, pain, and convalescence and enhance recovery without increasing risks of complications. (Rasmussen, 2008)

An updated Cochrane review of injection therapies (ESIs, facets, trigger points) for low back pain concluded that there is no strong evidence for or against the use of any type of injection therapy, but it cannot be ruled out that specific subgroups of patients may respond to a specific type of injection therapy. (Staal-Cochrane, 2009) Recent studies document a 629% increase in expenditures for ESIs, without demonstrated improvements in patient outcomes or disability rates. (Deyo, 2009) There is fair evidence that epidural steroid injection is moderately effective for short-term (but not long-term) symptom relief. (Chou3, 2009) This RCT concluded that caudal epidural injections containing steroids demonstrated better and faster efficacy than placebo. (Sayegh, 2009)

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. Objective findings on examination need to be present. For unequivocal evidence of radiculopathy, see AMA Guides, 5th Edition, page 382-383. (Andersson, 2000)

(2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants)

(3) Injections should be performed using fluoroscopy (live x-ray) and injection of contrast for guidance

(4) Diagnostic Phase: At the time of initial use of an ESI (formally referred to as the "diagnostic phase" as initial injections indicate whether success will be obtained with this treatment intervention), a maximum of one to two injections should be performed. A repeat block is not recommended if there is inadequate response to the first block (< 30% is a standard placebo response). A second block is also not indicated if the first block is accurately placed unless: (a) there is a question of the pain generator; (b) there was possibility of inaccurate placement; or (c) there is evidence of multilevel pathology. In these cases a different level or approach might be proposed. There should be 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) Therapeutic phase: If after the initial block/blocks are given (see "Diagnostic Phase" above) and found to produce pain relief of at least 50-70% pain relief for at least 6-8 weeks, additional blocks may be required. This is generally referred to as the "therapeutic phase." Indications for repeat blocks include acute exacerbation of pain, or new onset of symptoms. The general consensus recommendation is for no more than 4 blocks per region per year. (CMS, 2004) (Boswell, 2007)

(8) Repeat injections should be based on continued objective documented pain relief, decreased need for pain medications, and functional response

(9) Current research does not support a routine use of a “series-of-three” injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections for the initial phase and rarely more than 2 for therapeutic treatment

(10) It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or sacroiliac blocks or lumbar sympathetic blocks or trigger point injections as this may lead to improper diagnosis or unnecessary treatment

(11) Cervical and lumbar epidural steroid injection should not be performed on the same day. (Doing both injections on the same day could result

The AMA Guides (5th edition)

“...For reflex abnormalities to be considered valid, the involved and normal limb(s) should show marked asymmetry...”

“Weakness and Loss of Sensation

“To be valid, the sensory findings must be in a strict anatomic distribution, i.e follow dermatomal patterns...Motor findings should be consistent with the affected nerve structures(s). Significant, long standing weakness is usually accompanied by atrophy.”

“Radiculopathy

Radiculopathy for the purposes of the Guides is defined as significant alteration in the function of a nerve root or nerve roots and is usually caused by pressure on one or several nerve roots. The diagnosis requires a dermatomal distribution of pain, numbness, and/or paresthesias in a dermatomal distribution. The diagnosis of herniated disc must be substantiated by an appropriate finding on the imaging study. The presence of findings on a imaging study in and of itself does not make the diagnosis of radiculopathy. There must also be evidence as described above. “

“Atrophy

Atrophy is measured with a tape measure at identical levels on both limbs. For reasons of reproducibility, the difference in circumference should be 2cm or greater in the thigh and 1cm or greater in the arm, forearm, or leg...”

“Electrodiagnostic verification of Radiculopathy

Unequivocal electrodiagnostic evidence of acute nerve root pathology includes the presence of multiple positive sharp waves or fibrillation potentials in muscles innervated by one nerve root. However the quality of the person performing and interpreting the study is critical. Electromyography should be performed only by a licensed physician qualified by reason of education, training and experience in these procedures. Electromyography does not detect all compressive radiculopathies and cannot determine the cause of the nerve root pathology. On the other hand, electromyography can detect noncompressive radiculopathies, which are not identified by imaging studies. “

Page 382, AMA Guides to the Evaluation of Permanent Impairment. 5th edition

Epidural steroid injections, diagnostic (lumbar section)

Recommended as indicated below. Diagnostic epidural steroid transforaminal injections are also referred to as selective nerve root blocks, and they were originally developed as a

diagnostic technique to determine the level of radicular pain. In studies evaluating the predictive value of selective nerve root blocks, only 5% of appropriate patients did not receive relief of pain with injections. No more than 2 levels of blocks should be performed on one day. The response to the local anesthetic is considered an important finding in determining nerve root pathology. (CMS, 2004) (Benzon, 2005) When used as a diagnostic technique a small volume of local is used (<1.0 ml) as greater volumes of injectate may spread to adjacent levels. When used for diagnostic purposes the following indications have been recommended

- 1) To determine the level of radicular pain, in cases where diagnostic imaging is ambiguous, including the examples below
- 2) To help to evaluate a pain generator when physical signs and symptoms differ from that found on imaging studies;
- 3) To help to determine pain generators when there is evidence of multi-level nerve root compression;
- 4) To help to determine pain generators when clinical findings are consistent with radiculopathy (e.g., dermatomal distribution) but imaging studies are inconclusive
- 5) To help to identify the origin of pain in patients who have had previous spinal surgery.

Epidural steroid injections (ESIs) (Pain Section)

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

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- 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.

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

ACOEM-AMERICA 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: The AMA Guides (5th edition))