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NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:

Aug/05/2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Thoracic ESI, T8/T9 (62310)

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
Subspecialty Board Certified in Electrodiagnostic Medicine
Residency Training PMR and Orthopedic Surgery

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

ODG Guidelines and Treatment Guidelines
Adverse Determination Letters, 7/20/09, 7/28/09
MD, 2/23/09, 3/3/09, 4/1/09,
FNP, 4/21/09, 6/4/09, 6/8/09
MD, 5/18/09
MRI Thoracic Spine, 6/16/09
ODG-TWC, Neck and Upper Back

PATIENT CLINICAL HISTORY SUMMARY

This is a woman injured in xx/xxxx. She apparently had compression fractures. A procedure note described her as "presenting for #1 in a series of three epidural steroid injections..." The first injection was done at T8/T9. It apparently provided some relief. She had a second injection done at T8/T9 on 4/1/09. The indication states in the procedure note: "Patient is a female presenting for #2 in a series of three trans-laminar epidural steroid injections." Another injection was performed at T4/5 on 5/18/09 for pain after a compression fracture. She had an MRI on 6/16/09 that showed a hemangioma at T4/9 and wedge fractures at T3/4, an old wedge fracture at T6, and slight ones at T7 and T8 with a Schmorl's node. There is also spondylosis at T5/6, T3/4, with paracentral disc protrusion at T7/8 (with foraminal narrowing) and T9/10 and T10/11 that reaches the thecal sac, but not the cord. She has

ongoing pain. Mr. noted on 7/8/09 that there could be an infection or tumor at T9. This was considered a possible hemangioma, but doubts exist. This request is for a third injection at T8/T9.

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

The role of epidural injections as per the ODG is for the treatment of radicular pain. The pain in this case was described as mid back pain, and not radicular pain, except for the anterior chest pain in July 2009. The requested ESI is to be the third in a series. The procedure notes listed the plan for a series of 3 at the T8/T9 site. However, there was no radicular pain. In addition, a series of 3 ESIs is not generally approved by the ODG. The ODG states: "There is little to no guidance in current literature to suggest the basis for the recommendation of a third ESI, and the routine use of this practice is not recommended." For these reasons, the request does not meet the ODG for ESI. The reviewer finds that medical necessity does not exist for Thoracic ESI (62310).

Epidural steroid injections (ESIs), therapeutic

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) 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)

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 in an excessive dose of steroids, which can be dangerous, and not worth the risk for a treatment that has no long-term benefit.)

Epidural steroid injections, “series of three”

Not recommended. Original recommendations that suggested a “series of three injections” generally did so prior to the advent of fluoroscopic guidance. These previous recommendations were based primarily on case studies and anecdotal evidence (Class IV and V data). (Abram, 1999) (Warr, 1972) (Hickey, 1987) There does not appear to be any evidence to support the current common practice of a series of injections. (Novak, 2008) Contemporary research studies with higher levels of evidence (including two controlled trials) have suggested that on average, two or less ESIs are required in patients with successful outcomes from the use of ESIs to treat disc related lumbar radiculopathy. (Lutz, 1998) (Vad, 2002) (Riew, 2000) While all of these latter studies have utilized repeat injections, there has been no evidence-based research to explain why this practice is required, or the mechanism for possible action. Since the introduction of fluoroscopically guided ESIs, it has been suggested that there is little evidence to repeat an accurately placed epidural injection in the presence of mono-radiculopathy, regardless of whether there is partial or no response. (McLain, 2005) A recent randomized controlled trial of blind ESIs found no evidence to support repeat injections, because at six weeks there was no significant difference found between the ESI group and a placebo controlled group in terms of any measured parameter. (Price, 2005)

A repeat injection has been suggested if there is question of accurate dermatomal diagnosis, if pain may be secondary to a different generator, or in the case of multilevel pathology. (McLain, 2005) There is a lack of support for 2nd epidural steroid injection if the 1st is not effective. (Cuckler, 1985) With fluoroscopic guidance, there is little support to do a second epidural if there is no response to the first injection. **There is little to no guidance in current literature to suggest the basis for the recommendation of a third ESI, and the routine use of this practice is not recommended.**

Epidural steroid injections, diagnostic

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.

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)