Applied Assessments LLC

An Independent Review Organization
1124 N. Fielder Road, #179, Arlington, TX 76012
(512) 772-1863 (phone)
(512) 857-1245 (fax)

Notice of Independent Review Decision

DATE OF REVIEW: JULY 18, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

ACS Services

A 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

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 or not medical necessity exists for each of the health care services in dispute.

The reviewer finds that medical necessity does not exist for ACS Services.

PATIENT CLINICAL HISTORY [SUMMARY]:

This is a xx year old man who apparently was injured on xx/xx/xx. He was lifting a heavy crate or pallet from a fork lift. He felt sudden pain in his neck and low back. The material provides some confusing and conflicting information afterwards. Some of his problems were felt to be due to aging changes, but others felt he had a lumbar disc herniation. Most of his neck problem improved after an anterior cervical fusion from C3 to C6 in 2003. The ongoing symptoms and questions relate to his lower back. He has diabetes. Electrodiagnostic studies were limited to the upper extremities and were performed in 2002.

He apparently has had variable symptoms. He had back pain and subjective leg weakness in 2003. Dr. noted in 9/24/04 that he had neck and back pain without

radiation to his arms and legs. Notes in 2005 report left lower extremity symptoms. He described burning in his feet. No one apparently considered diabetic neuropathy for the bilateral symptoms.

He had MRIs on 2/25/02 that showed a disc protrusion with out nerve compression or facet arthropathy. An MRI on 3/31/06 showed some epidural fat compressing the thecal sac at L5/S1, but the radiologist felt that this was "of uncertain significance." Another MRI 6/12/07 was interpreted as normal except for some Schmorl nodules. Read by another radiologist, it was reported as showing unchanged epidural fat again of questionable significance.

An attempt at a microdiscectomy at L5/S1 in 2004 was not completed due to technical problems with the procedure. He underwent a bilateral decompression laminectomy at L5/S1 in November 2007 with reported transient improvement. His leg pain was better. Dr. advised a repeat epidural injection for ongoing back pain. He felt that the pain was mechanical (4/9/08).

He had a total of 5 lumbar or caudal epidural injections. Those done prior to surgery provided better relief than those performed after his surgery. The original reportedly gave him several months of relief. (Dr. reported 4 months after 4 ESIs in 2004). His most recent was a caudal epidural injection by Dr. on February 14, 2008. Dr. saw him 2 weeks after the procedure and described improvement. Yet this was not lasting.
Dr. would like to perform a high volume caudal ESI. The examinations describe low back pain and tenderness at L5/S1. There is little recent description of any objective neurological loss. He had some anterior thigh sensory changes at L3.

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

The reviewer finds that medical necessity does not exist for ACS Services.

The reviewer is not fully clear of Dr. plans for the High Volume Caudal ESI, and the reviewer could not find an explanation in the massive amount of material presented.

First, the caudal approach is preferred after surgery. This different site of the injections may have some bearing on the different outcomes. The High volume approach has extra risks to the brain and CNS based upon the volume given. Again, this was not discussed. Epidural injections are more effective for radiculopathy than for mechanical back pain. Dr. felt the pain is from mechanical back pain. Although the patient had some dysesthesias in the anterior thigh, there was no other description of a radiculitis or radiculopathy. The thigh symptoms are at a nerve root level above the surgery and questionable radiological findings. The ODG guides precludes the use of repeated ESIs and for ESIs for nonradicular pain. The reviewer thinks that Dr. is considering the large volume for the lysis of adhesions following the prior lumbar laminectomy. The ODG considers this experimental. The reviewer finds neither reason to justify the repeat ESIs from the material provided.

Adhesiolysis, percutaneous
Under study. Also referred to as epidural neurolysis, epidural neuroplasty, or lysis of epidural adhesions, percutaneous adhesiolysis is a treatment for chronic back pain that involves disruption, reduction, and/or elimination of fibrous tissue from the epidural space. Lysis of adhesions is carried out by catheter manipulation and/or injection of saline (hypertonic saline may provide the best results). Epidural injection of local anesthetic and steroid is also performed. It has been suggested that the purpose of the intervention is to eliminate the effect of scar formation, allowing for direct application of drugs to the involved nerves and tissue, but the exact mechanism of success has not been determined. There is a large amount of variability in the technique used, and the technical ability of the physician appears to play a large role in the success of the procedure. In addition, research into the identification of the patient who is best served by

this intervention remains largely uninvestigated. Adverse reactions include dural puncture, spinal cord compression, catheter shearing, infection, excessive spinal cord compression, hematoma, bleeding, and dural puncture. Duration of pain relief appears to range from 3-4 months. Given the limited evidence available for percutaneous epidural adhesiolysis it is recommended that this procedure be regarded as investigational at this time. (Gerdesmeyer, 2003) (Heavner, 1999) (Belozer, 2004) (BlueCross BlueShield, 2004) (Belozer, 2004) (Boswell, 2005) (The Regence Group, 2005) (Chopra, 2005) (Manchikanti1, 2004) This recent RCT found that after 3 months, the visual analog scale (VAS) score for back and leg pain was significantly reduced in the epidural neuroplasty group, compared to to conservative treatment with physical therapy, and the VAS for back and leg pain as well as the Oswestry disability score were significantly reduced 12 months after the procedure in contrast to the group that received conservative treatment. (Veihelmann, 2006)
Preliminary suggested criteria for percutaneous adhesiolysis while under study:
- The 1-day protocol is preferred over the 3-day protocol.
- All conservative treatment modalities have failed, including epidural steroid injections.
- The physician intends to conduct the adhesiolysis in order to administer drugs closer to a nerve.
- The physician documents strong suspicion of adhesions blocking access to the nerve.
- Adhesions blocking access to the nerve have been identified by Gallium MRI or Fluoroscopy during epidural steroid injections

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)
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) (Delport, 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.

Criteria for the use of Epidural steroid injections:

Note: The purpose of ESI is to reduce pain and inflammation, restoring range of motion and 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 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.)

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**

- [x] **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- [ ] **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- [ ] **MILLIMAN CARE GUIDELINES**
- [x] **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)**