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NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:
Sep/09/2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Right L5/S1 Caudal Epidural Lysis

DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
Board Certified in Physical Medicine and Rehabilitation
Subspecialty Board Certified in Pain Management
Subspecialty Board Certified in Electrodiagnostic Medicine
Residency Training PMR and ORTHOPAEDIC SURGERY

REVIEW OUTCOME:

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

[X] Upheld (Agree)

[ ] Overturned (Disagree)

[ ] Partially Overturned (Agree in part/Disagree in part)

INFORMATION PROVIDED TO THE IRO FOR REVIEW
OD Guidelines
Denial Letters 6/22/09 and 8/8/09
Letter from Dr. 7/16/09
11/21/07 thru 5/20/09
MRI 4/29/09
Physicians 6/22/09

PATIENT CLINICAL HISTORY SUMMARY
This xx-year-old woman had back pain and underwent a laminectomy and fusion in 2008. The April 2009 note from Dr. noted her improvement. She subsequently developed back pain and right lower extremity pain. The examination showed pan on motion with pain and reduced sensation and weakness on SLR. (The Reviewer presumes that these were done separate from the SLR). The MRI on 4/29/09 showed the fusion from L4 to S1, with degenerative changes at L3/4. The report stated “There is evidence of epidural firosis without significant mass effect upon the thecal sac.”

The Cervical issues and migraine issues are not the focus of this discussion.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDING CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION
Dr. 's letter of rebuttal stated that evidence based medicine used by Dr. used was wrong. His evidence to refute the denial is the work done by Dr. , of . The instructions from the Texas Workers" Compensation in the Department of Insurance is to utilize the ODG as basis of the evidence based medicine. Dr. states that the ODG supports the lysis of adhesions. The Reivewer is enclosing the most recent section of the ODG, down loaded on Friday, September 4, 2009. This is essentially the same by Dr. It clearly says that the procedure is "Not recommended due to the lack of sufficient literature evidence." It is considered investigational at this time. The ODG states that there is a large variability in outcomes due to the different techniques used. Dr. plans the lysis according to the techniques developed by Dr. Dr. was not cited in the review. For anecdotal purposes, the Reviewer have seen a couple of patients successfully treated by Dr. The Reviewer has not personally met Dr. .

That being said, the ODG will accept the procedure as an investigational one when certain criteria are met. The Reviewer highlighted the criteria include unsuccessful epidural steroid injections as part of the failed conservative treatments. The ESIs and other conservative treatments were not reported as having been attempted by Dr. . Therefore, the patient has not met the criteria for the procedure as established in the ODG.

Adhesiolysis
See the Low Back Chapter

Lysis of epidural adhesions
See Adhesiolysis.

Adhesiolysis, percutaneous
Not recommended due to the lack of sufficient literature evidence (risk vs. benefit, conflicting literarure). 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) (Boswell, 2007) (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.

That being said, the ASIPP has established evidence based guidelines supporting the use of the procedure. Pain Physician Volume 6, 2003
"Moderate to strong evidence was shown for multiple therapeutic interventional techniques including medial branch blocks and medial branch neurotomy; caudal epidural steroid injections and transforaminal epidural steroid injections; lumbar percutaneous adhesiolysis; and implantable therapies"

Pain Physician Volume 12: July/August 2009. Pp 735-737

6.3 Lumbar Epidural Adhesiolysis

The purpose of percutaneous epidural lysis of adhesions is to minimize the deleterious effects of epidural scarring, which can physically prevent direct application of drugs to nerves and other spinal tissues and to treat chronic back pain (872-875). Epidural lysis of adhesions and direct deposition of corticosteroids in the spinal canal can also be achieved with a 3-dimensional view provided by epiduroscopy or spinal endoscopy.

6.3.1 Percutaneous Adhesiolysis

6.3.1.1 Evidence Assessment

Clinical effectiveness of percutaneous adhesiolysis was evaluated in 3 systematic reviews (43,46,113), and one health technology assessment (872). Epter et al (43) concluded that the indicated level of evidence is I or II-1 for short- and long-term relief for percutaneous adhesiolysis in post lumbar surgery syndrome. Three randomized trials (876-878) and 4 observational studies (879-882) met inclusion criteria for percutaneous adhesiolysis. Of the 3 randomized trials (876-878), 2 studies had similar patient characteristics (877,878). Manchikanti et al (878) reported that patients in all 3 studies failed multiple conservative modalities of treatments including fluoroscopically directed epidural steroid injections. They (878) also reported the proportion of patients included with a history of previous surgery ranged from 64% to 72% in all intervention groups.
Heavner et al (877) compared various types of solutions. Solutions used after mechanical adhesiolysis; Group A received a combination of hyaluronidase and hypertonic saline; Group B, hypertonic saline solution; Group C, isotonic saline solution; and Group D, hyaluronidase and isotonic saline solution. Heavner et al (877) evaluated a 3-day procedure where the catheter was inserted on the first day and the drugs were injected on the second and third day, whereas Manchikanti et al (878,882) evaluated one-day adhesiolysis. Veihelmann et al (876) and Gerdesmeyer et al (879) used a 3-day protocol in both studies. They also used hyaluronidase as part of the treatment protocol. The outcome parameters by Heavner et al (877) included the short-form MPQ and VAS for back pain and leg pain. Manchikanti et al (878) utilized VAS pain scale, ODI 2.0, work status, opioid intake, range of motion measurement, and psychological evaluation by Pain Patient Profile (P-3). Veihelmann et al (876) used VAS scores for back pain and leg pain, ODI score, Gerbershagen score, and a quantified score for the use of analgesics. They also used a blinded observer.

Manchikanti et al (878) divided 75 patients randomly into 3 groups, with Group I consisting of a control group without adhesiolysis, with injection of local anesthetic, steroid, and normal saline; Group II consisting of patients undergoing adhesiolysis, with injection of local anesthetic, steroid, and normal saline; and Group III consisting of patients undergoing adhesiolysis, with an injection of 10% sodium chloride solution, in addition to local anesthetic and steroid. The descriptive characteristics of observational studies are well described in the systematic review by Epter et al (43)….

6.3.1.4 Indications

Indications for lysis of epidural adhesions are chronic low back and/or lower extremity pain resulting from post surgery syndrome, epidural fibrosis, and spinal stenosis.

6.3.1.5 Level of Evidence

Table 19 illustrates the results of published studies of effectiveness of percutaneous adhesiolysis.

The effectiveness of percutaneous adhesiolysis in the management of chronic low back pain in post lumbar surgery syndrome indicated Level I to II-1 evidence

6.3.1.6 Recommendations

The recommendation is strong, with 1B or 1C based on the USPSTF criteria (126) for percutaneous adhesiolysis in post lumbar surgery syndrome.

There is obvious differences of acceptance of the evidence based guidelines. Since DWCC prefers the ODG, the Reviewer must rely upon it. The procedure is denied for the reasons cited above.

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

[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 ERVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)

[ ] OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)