



Medical Review Institute of America, Inc.
America's External Review Network

DATE OF REVIEW: April 16, 2009

IRO Case #:

Description of the services in dispute:

Preauthorization – cervical and lumbar epidural steroid injections.

A description of the qualifications for each physician or other health care provider who reviewed the decision

The physician who provided this review is a fellow of the American Board of Orthopaedic Surgery. This reviewer is a fellow of the North American Spine Society and the American Academy of Orthopaedic Surgeons. This reviewer has been in active practice since 1990.

Review Outcome

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

be: Upheld

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.

Medical necessity does not exist for the requested cervical and lumbar epidural steroid injections.

Information provided to the IRO for review

Records Received From The State:

Patient clinical history [summary]

The patient is a xx-year-old female who is reported to have sustained an injury to her low back on xx/xx/xx. On this date, she is reported to have fallen off a ladder in a freezer in the bakery. She

reports injuries to her buttocks and low back.

The patient was initially evaluated by Dr. on 04/09/08. She is reported to have complaints of neck and low back pain. She reports falling off of a ladder at work. She hit her right hip on a shelf when she was falling, and hit her back on the floor. She complains of right hip pain, low back pain, and left sided neck pain. Her back pain is moderate, and she has pain in her right leg down to the ankle. She reports some mild numbness in the right hip and low back. She is reported to be a current tobacco user, smoking 2 packs per day. On physical examination she is 61 inches tall and weighs 150 pounds. She is relaxed, cooperative and alert. She is tender over the left cervical paraspinal muscles and over the left trapezius muscle. She has limited cervical range of motion, and she has negative Spurling's, negative Lhermitte's. Motor strength is graded as 5/5 throughout the bilateral upper extremities. Sensation is intact. Reflexes are 1+ and symmetric bilaterally. She is tender to palpation in the lumbar paraspinal muscles, right greater than left. She is tender over the right greater trochanter. Lumbar range of motion is reduced. Straight leg raise is negative. Lower extremity motor strength is graded as 5/5. Patellar and Achilles reflexes are 1+ and symmetric. Sensation is intact. She has full range of motion at the hips without pain. Cervical and lumbar radiographs are negative for fractures. There is mild spondylosis.

On 04/22/08 the patient was subsequently seen by Dr. . She has complaints of neck and low back pain. It is reported that she was taken by ambulance to , where she had x-rays, CT scan and orthopedic evaluation. She was seen by Dr. , who recommended physical therapy and sedentary work. On physical examination the patient has cervical tenderness of the paracervical muscles bilaterally. Cervical range of motion is reduced. Shoulder depression test is reported to be positive on the left. Cervical compression test is reported to be positive on the left. Lumbar range of motion is reduced. Tenderness over the lumbar midlines and paraspinal muscles bilaterally and right sciatic notch. Straight leg raise is reported to be positive bilaterally on the right side. Pain is referred to the right lower leg. There is diminished sensation over L5 and S1 on the right greater at L5. The patient subsequently was diagnosed with cervical radiculitis, lumbar radiculitis and recommended to undergo 12 sessions of therapy. She was provided oral medications, and she subsequently was referred for MR imagery.

On 05/13/08 the patient underwent MRIs of both the cervical and lumbar spines. The MRI of the cervical spine reports a 1 mm broad based disc bulge with 50 percent neural foraminal stenosis on the right at C3-4. At C4-5 there is a 2 mm broad based disc bulge associated with 50 percent neural foraminal stenosis on the right and 40 percent on the left. Partial desiccation of the disc material is seen. At C5-6 there is no significant abnormality and at C6-7 there is a 2 mm a centric disc bulge bilaterally with no significant canal stenosis and no significant abnormality. MRI of the lumbar spine reports no disc abnormalities from T12-L1 through L2-3. At L3-4 there is mild lateral recess stenosis on the right due to facet hypertrophy. There is a 1 mm broad based disc bulge with minimal central canal stenosis. At L4-5 there is a 1.5 mm broad based disc bulge associated with facet hypertrophy and somewhat thick ligamentum flavum causing moderate stenosis at the lateral recess and central canal. At L5-S1 there is a 2.5 mm broad based disc bulge protrusion displacing

the S1 nerve roots anteriorly, bilaterally there is facet hypertrophy seen causing stenosis of the central canal and lateral recess.

Records include an EMG/NCV study of the cervical spine performed on 06/10/08. The patient is reported to have neck pain along with intermittent radicular symptoms down both arms. A review of the EMG reports normal insertional activity, normal fibrillations, normal amplitude, normal duration, and no polyphasic in the left upper extremity. This study was completely normal. Nerve conduction studies were performed and the evaluator Dr. reports that both motor and sensory neuroconduction studies have normal distal latencies, amplitudes and conduction velocities for bilateral radial, medial and ulnar nerves. The F-wave latencies were in normal limits. This would be interpreted as a normal nerve conduction velocity. No abnormalities were found on EMG; however, Dr. reports that the patient has symptoms consistent with irritation of the C6 and C8 nerve roots which are not validated by his electrodiagnostic study.

On 06/16/08 the patient underwent a lower extremity EMG/NCV. This consists of a report which indicates that there are 1+ fibrillations with increased insertional activity for the peroneus longus muscle as well as the medial gastroc and lower paraspinous muscles. This was felt to be consistent with a subacute right S1 radiculopathy. On 04/14/08 the patient was subsequently evaluated by Dr. . On examination there are no specific findings documented. She is diagnosed with cervicalgia and lumbar pain and left shoulder pain. She is recommended to continue her current medications.

On 09/10/08 the patient was seen by Dr. . Dr. discusses the information previously noted. On physical examination there is mild to moderate tenderness of the cervical spine with slight tenseness of the musculature. There is painful range of motion slightly decreased in all directions. Upper extremity reflexes are present. Sensory is grossly intact. Grip strength is decreased in the left hand when compared to the right. Motor strength is graded as 5/5. Examination of the lumbosacral spine reveals some mild to moderate tenderness to palpation. There was slight tenseness of the musculature. There was painful range of motion. Achilles and patellar reflexes were present. Straight leg raises were positive on the left and negative on the right. She was able to heel-toe walk without difficulty. Musculature was graded as 4/5 on the left and 5/5 on the right. There is decreased sensation in the L5-S1 dermatome on the left. The patient is diagnosed with bulging discs in both the lumbar and cervical spines, lumbar radiculopathy and cervical radiculopathy. She was provided oral medications and prescription for a walker. In 10/01/08 the patient underwent lumbar epidural steroid injections performed by Dr. . The level is not documented.

On 10/08/08 the patient was seen in follow up by Dr. . She is reported to be pending an epidural steroid injection no. 2 to the cervical spine. The patient was seen in follow up by Dr. on 10/15/01. She is reported to be status post an L5-S1 epidural block on 10/01/08. She reports that it did not help with her pain whatsoever. On examination she has tenderness to palpation over the paraspinous musculature. She has a positive straight leg raise on the right. Reflexes in the lower extremities are normal. Motor strength is 4+ on the left and 5 on the right. She is sensory intact.

The patient continued to follow up with Dr. [redacted] and Dr. [redacted].

On 12/10/08 it is reported that the patient received no relief from her L5–S1 epidural block and she continues to have ongoing pain in her back with radiation into the lower extremities. The record includes a letter of appeal from Dr. [redacted] dated 01/23/09. He reports that a request for additional epidural steroid injections at L4–5 bilaterally was denied due to no EMG/NCV provided and there was no neural compressive lesion on the patient's MRI at L4–5. Dr. [redacted] opines that the patient is a candidate for lumbar epidural steroid injections.

On 02/26/09 the patient was evaluated by Dr. [redacted]. She reports that she was seen in an emergency room and was subsequently treated and released. She saw a company doctor for one visit and after that time she saw Dr. [redacted] and was started on a physical therapy program. She was referred to Dr. [redacted] and one epidural steroid injection was performed. She has complaints of 7/10 cervical pain with occasional tingling to both hands. She has complaints of 8/10 lumbar pain with occasional numbness in both lower extremities. On examination she is reported to be well developed and well nourished. She ambulates with the use of a cane. She has decreased cervical range of motion, midline tenderness and palpable spasms posteriorly. Her upper extremity motor reflexes are 2+ and symmetric. She has some paresthesias in both upper extremities but her motor strength was symmetric. Lumbar spine is tender in the midline. She has a positive straight leg raise bilaterally. She has tenderness and spasms in the mid portion of her lumbar spine. Her lower extremity motor strength and sensation were intact. Her patellar and Achilles reflexes were 2+ and symmetric. MRI is discussed and EMG is referred to and reported to show evidence of nerve root irritation at C6–7. Dr. [redacted] recommends cervical epidural steroid injections and lumbar epidural steroid injections with the patient to be referred for post injection rehabilitation. He opines that the patient is not an operative candidate at this time.

On 03/13/09 the request was reviewed by Dr. [redacted]. Dr. [redacted] opines that the patient does not have evidence of objectively affirmed cervical or lumbar radiculopathy. The documented clinical examination is not indicative of findings consistent with radiculopathy. He subsequently found the request to be not medically necessary. On 03/20/09 this case was reviewed by Dr. [redacted]. Dr. [redacted] notes that the patient is without objective clinical evidence of radiculopathy. She reports review of this report shows no definitive evidence of radiculopathy. She opines there is no information provided on which to overturn the previous adverse determination.

Analysis and explanation of the decision include clinical basis, findings and conclusions used to support the decision.

The request for cervical and lumbar epidural steroid injections is not supported by the submitted clinical information and previous reviewer's determinations are upheld. The available medical records indicate that the patient initially sustained an injury to her low back and neck on xx/xx/xx after a fall in the workplace. The patient was initially evaluated by Dr. [redacted] on 04/09/08, and other than for myofascial pain, her examination is normal and shows no evidence of either a cervical or lumbar radiculopathy. The patient subsequently sought care from the [redacted] approximately 2 weeks after

Dr. 's evaluation and she is now reported to have positive findings, not evidenced on Dr. 's examination to include positive shoulder depression test, positive cervical compression test with radiation into the left and positive straight leg raising bilaterally, with pain referred to the right lower leg and diminished sensation over the L5-S1 on the right greater at L5. The change in examination is fairly significant between providers. The patient was later referred for MRI of both the cervical and lumbar spines which report multi level broad based disc bulges but no overt herniations in the cervical spine. In regards to the lumbar spine, there is stenosis caused by degenerative findings and ligamentum flavum hypertrophy. However, at L5-S1 there is a broad based disc bulge, which does contact the S1 nerve roots anteriorly and bilaterally. The patient was then referred for EMG/NCV study. This study was entirely normal and Dr. 's conclusions are inappropriate. There is no evidence of a cervical radiculopathy on this study and it is further noted that there was no testing of the cervical paraspinal musculature. The patient was then again referred for electrodiagnostic studies which do report a subacute right S1 radiculopathy and this is consistent with the EMG findings reported. The patient subsequently came under the care of Dr. and Dr. and underwent a lumbar epidural steroid injection at L5-S1 on 10/01/018. The patient received absolutely no relief from this. The patient's care subsequently has now been changed to Dr. . He evaluated the patient on 02/26/09. Dr. 's examination does not show any objective evidence of either a cervical or lumbar radiculopathy. Current evidence based guidelines require that there be clear objective evidence of a radiculopathy prior to the performance of epidural steroid injections. Objective physical evidence is required, and this may be supplemented with EMG/NCV studies. In regards to the cervical spine, the patient does not have objective evidence of a cervical radiculopathy and she has negative EMG/NCV study. Current evidence based guidelines would not support the performance of cervical epidural steroid injections in this case. In regards to the lumbar spine the patient has objective evidence on imaging study indicating compression of the bilateral S1 nerve roots. The patient appropriately was referred for electrodiagnostic studies confirming the presence of an S1 radiculopathy. The patient received a single epidural steroid injection on 10/01/08, and post procedurally she had no response to this injection. Current evidence based guidelines require that the patient receive at least 50 percent relief to warrant the performance of a second lumbar epidural steroid injection. It is clear that the patient did not achieve any significant relief from this injection and so therefore further additional lumbar epidural steroid injections would not be medically necessary or supported by the ODG. While the previous reviewer's conclusions are brief, they are, in fact, accurate and in accordance with the official disability guidelines. Therefore, the request for cervical and lumbar epidural steroid injections is not considered medically necessary.

A description and the source of the screening criteria or other clinical basis used to make the decision:

The Official Disability Guidelines, 13th edition, The Work Loss Data Institute:

Cervical 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) 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;

(4) To help to identify the origin of pain in patients who have had previous spinal surgery.

Lumbar ESI: 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) (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)

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.)