

Case Number:	CM15-0091633		
Date Assigned:	05/15/2015	Date of Injury:	11/09/1995
Decision Date:	09/23/2015	UR Denial Date:	04/30/2015
Priority:	Standard	Application Received:	05/11/2015

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
 State(s) of Licensure: California
 Certification(s)/Specialty: Physical Medicine & Rehabilitation

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 54 year old male, who sustained an industrial injury on 11/09/1995. Diagnoses include worsening back/leg pain, spondylolisthesis L3-4 severe L5-S1 and leg weakness/foot drop. Treatment to date has included diagnostics, medications including anti-inflammatories, bracing, epidural injections and surgical intervention (2 spinal surgeries (2002) no operative notes available). Per the Primary Treating Physician's Progress Report dated 4/16/2015, the injured worker reported low back pain, bilateral leg pain with numbness and weakness, mid back pain and neck pain and worsening severe back pain right side worse than left side, over the course of the last year getting worse despite conservative care. Pia is rated as 9/10 on a subjective scale. Physical examination revealed an antalgic gait; he uses a cane for ambulation. There were absent ankle reflexes, strength was noted as 3/5 upon motor testing and there was sensory loss in the L5-S1 distribution. The plan of care included diagnostics and topical and oral medications and authorization was requested for Ketamine 5% cream, Morphine sulfate ER and Baclofen tabs 10mg.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

Ketamine 5% cream 60gm - apply to affected area TID #2: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Ketamine Page(s): 113.

Decision rationale: This patient presents with chronic low back, bilateral leg, mid back and neck pains with worsening symptoms with work injury from 11/9/95. The request is for Ketamine 5% cream 60gm - apply to affected area TID #2. 4/16/15 report states that the patient has 80% of pain in the low back with 20% of symptoms going into the legs. The patient has had ESI's, and two spinal surgeries from 2002. Current medications include Cymbalta, Ketamine cream, Ambien, Baclofen, Butalbital, Viagra, Simvastatin and Morphine. MRI is from 7/20/12 that showed surgical changes from L4-S1 with bilateral pedicle screws. Moderate bilateral foraminal stenoses were noted at L3-4 per spinal surgeons reading but as read by radiologist, "moderate bilateral facet arthrosis and ligamentous hypertrophy" are noted at L3-4. X-rays showed 3mm spondylolisthesis at L3-4. MTUS page 113, Ketamine section discussing its topical use states "Under study: Only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted. Topical ketamine has only been studied for use in non-controlled studies for CRPS I and post-herpetic neuralgia and both have shown encouraging results. The exact mechanism of action remains undetermined. (Gammaitoni, 2000) (Lynch, 2005) See also Glucosamine (and Chondroitin Sulfate)." In this case, the patient does not present with CRPS nor post-herpetic neuralgia for which topical Ketamine might be indicated. None of the reports discuss how this topical is being used with what effectiveness. Given the lack of its support from MTUS, the request IS NOT medically necessary.

Viagra 100mg 1 tab 1 hour before sexual activity #30: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.aetna.com/cpb/medical/data/1_99/0007.html.

Decision rationale: worsening symptoms with work injury from 11/9/95. The request is for Viagra 100mg 1 tab 1 hour before sexual activity #30. 4/16/15 report states that the patient has 80% of pain in the low back with 20% of symptoms going into the legs. The patient has had ESI's, and two spinal surgeries from 2002. Current medications include Cymbalta, Ketamine cream, Ambien, Baclofen, Butalbital, Viagra, Simvastatin and Morphine. MRI is from 7/20/12 that showed surgical changes from L4-S1 with bilateral pedicle screws. Moderate bilateral foraminal stenoses were noted at L3-4 per spinal surgeons reading but as read by radiologist, "moderate bilateral facet arthrosis and ligamentous hypertrophy" are noted at L3-4. X-rays showed 3mm spondylolisthesis at L3-4. MTUS, ACOEM and ODG guidelines are silent regarding this request. www.aetna.com/cpb/medical/data/1_99/0007.html does provide a discussion regarding erectile dysfunction and performance enhancing drugs such as Viagra. ODG guidelines Pain Chapter, under Opioids for chronic pain, "Adverse effects: These include serious fractures, sleep apnea, hyperalgesia, immunosuppression, chronic constipation, bowel

obstruction, myocardial infarction, and tooth decay due to xerostomia. Neuroendocrine problems include Hypogonadism, erectile dysfunction, infertility, decreased libido, osteoporosis, and depression. Men taking opioids, especially high doses and over several months, are about 50% more likely to fill a prescription for erectile dysfunction (ED), according to a study of over 11,000 men." Given the patient's Chronic opioid use, the patient may suffer from ED requiring treatment. However, AETNA Guidelines Clinical Polity Bulletin No. 0007 regarding erectile dysfunction state that a comprehensive physical/examination and lab workup for the diagnosis of erectile dysfunction(ED) including medical, sexual, and psychosocial evaluation is required. There is no documentation of hypo-gonadism that may contribute to the patient's ED. Testosterone level, for example is not provided. AETNA also does not support performance- enhancing drugs such as Viagra or Cialis. The request IS NOT medically necessary.

Lumbar epidurogram: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chronic Pain Treatment Guidelines epidural steroid injections (ESIs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Epidural steroid injections Page(s): 46, 47.

Decision rationale: This patient presents with chronic low back, bilateral leg, mid back and neck pains with worsening symptoms with work injury from 11/9/95. The request is for EPIDUROGRAM. 4/16/15 report states that the patient has 80% of pain in the low back with 20% of symptoms going into the legs. The patient has had ESI's, and two spinal surgeries from 2002. Current medications include Cymbalta, Ketamine cream, Ambien, Baclofen, Butalbital, Viagra, Simvastatin and Morphine. MRI is from 7/20/12 that showed surgical changes from L4-S1 with bilateral pedicle screws. Moderate bilateral foraminal stenoses were notes at L3-4 per spinal surgeons reading but as read by radiologist, "moderal bilateral facet arthrosis and ligamentous hypertrophy" are noted at L3-4. X-rays showed 3mm spondylolisthesis at L3-4. 2/24/15 report states that the patient is s/p ESI from 10/14/14 and "patient did have significant flare-up of pain on 12/04/14." 11/17/14 report states that the patient "continues to have good pain relief from epicural injection on 10/14/14. This helps with his radicular pain in the lower extremities and also some of his pain in the low back." MTUS guidelines page 46, 47 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 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. In this case, the patient presents with minimal leg symptoms with 80% of pain in the low back. While examination shows motor weakness at 3/5, there is no myotomal deficit. Furthermore, MRI does not show a clear evidence of nerve root potential lesion. Finally, the patient did have an ESI on 10/14/14 with some reduction of pain. However, there is no evidence that the patient experience 50% or more reduction of pain lasting more than 6 weeks with associated reduction of medication. Since repeat ESI is not indicated, there would be no need for an epidurogram. The request IS NOT medically necessary.

IV sedation: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chronic Pain Treatment Guidelines epidural steroid injections (ESIs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Epidural steroid injections Page(s): 46, 47.

Decision rationale: This patient presents with chronic low back, bilateral leg, mid back and neck pains with worsening symptoms with work injury from 11/9/95. The request is for IV SEDATION. 4/16/15 report states that the patient has 80% of pain in the low back with 20% of symptoms going into the legs. The patient has had ESI's, and two spinal surgeries from 2002. Current medications include Cymbalta, Ketamine cream, Ambien, Baclofen, Butalbital, Viagra, Simvastatin and Morphine. MRI is from 7/20/12 that showed surgical changes from L4-S1 with bilateral pedicle screws. Moderate bilateral foraminal stenoses were noted at L3-4 per spinal surgeons reading but as read by radiologist, "moderal bilateral facet arthrosis and ligamentous hypertrophy" are noted at L3-4. X-rays showed 3mm spondylolisthesis at L3-4. 2/24/15 report states that the patient is s/p ESI from 10/14/14 and "patient did have significant flare-up of pain on 12/04/14." 11/17/14 report states that the patient "continues to have good pain relief from epicural injection on 10/14/14. This helps with his radicular pain in the lower extremities and also some of his pain in the low back." MTUS guidelines page 46, 47 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 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. In this case, the patient presents with minimal leg symptoms with 80% of pain in the low back. While examination shows motor weakness at 3/5, there is no myotomal

deficit. Furthermore, MRI does not show a clear evidence of nerve root potential lesion. Finally, the patient did have an ESI on 10/14/14 with some reduction of pain. However, there is no evidence that the patient experience 50% or more reduction of pain lasting more than 6 weeks with associated reduction of medication. The current request for IV sedation would not be indicated since ESI is not. The request IS NOT medically necessary.

Additional level x2: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chronic Pain Treatment Guidelines epidural steroid injections (ESIs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Epidural steroid injections Page(s): 46, 47.

Decision rationale: This patient presents with chronic low back, bilateral leg, mid back and neck pains with worsening symptoms with work injury from 11/9/95. The request is for ADDITIONAL LEVEL X 2. 4/16/15 report states that the patient has 80% of pain in the low back with 20% of symptoms going into the legs. The patient has had ESI's, and two spinal surgeries from 2002. Current medications include Cymbalta, Ketamine cream, Ambien, Baclofen, Butalbital, Viagra, Simvastatin and Morphine. MRI is from 7/20/12 that showed surgical changes from L4-S1 with bilateral pedicle screws. Moderate bilateral foraminal stenoses were notes at L3-4 per spinal surgeons reading but as read by radiologist, "moderal bilateral facet arthrosis and ligamentous hypertrophy" are noted at L3-4. X-rays showed 3mm spondylolisthesis at L3-4. 2/24/15 report states that the patient is s/p ESI from 10/14/14 and "patient did have significant flare-up of pain on 12/04/14." 11/17/14 report states that the patient "continues to have good pain relief from epicural injection on 10/14/14. This helps with his radicular pain in the lower extremities and also some of his pain in the low back." MTUS guidelines page 46, 47 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 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. In this case, the patient presents with minimal leg symptoms with 80% of pain in the low back. While examination shows motor weakness at 3/5, there is no myotomal deficit. Furthermore, MRI does not show a clear evidence of nerve root potential lesion. Finally, the patient did have an ESI on 10/14/14 with some

reduction of pain. However, there is no evidence that the patient experience 50% or more reduction of pain lasting more than 6 weeks with associated reduction of medication. The patient's Morphine remained the same at 30mg dosage. The current request is for additional two levels for the requested ESI's are not indicated. The request IS NOT medically necessary.

Fluoroscopic guided lumbar epidural steroid injection L5-S1: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chronic Pain Treatment Guidelines epidural steroid injections (ESIs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Epidural steroid injections Page(s): 46, 47.

Decision rationale: This patient presents with chronic low back, bilateral leg, mid back and neck pains with worsening symptoms with work injury from 11/9/95. The request is for Fluoroscopic guided lumbar epidural steroid injection L5-S1. 4/16/15 report states that the patient has 80% of pain in the low back with 20% of symptoms going into the legs. The patient has had ESI's, and two spinal surgeries from 2002. Current medications include Cymbalta, Ketamine cream, Ambien, Baclofen, Butalbital, Viagra, Simvastatin and Morphine. MRI is from 7/20/12 that showed surgical changes from L4-S1 with bilateral pedicle screws. Moderate bilateral foraminal stenoses were noted at L3-4 per spinal surgeons reading but as read by radiologist, "moderal bilateral facet arthrosis and ligamentous hypertrophy" are noted at L3-4. X-rays showed 3mm spondylolisthesis at L3-4. 2/24/15 report states that the patient is s/p ESI from 10/14/14 and "patient did have significant flare-up of pain on 12/04/14." 11/17/14 report states that the patient "continues to have good pain relief from epicural injection on 10/14/14. This helps with his radicular pain in the lower extremities and also some of his pain in the low back." MTUS guidelines page 46, 47 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 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. In this case, the patient presents with minimal leg symptoms with 80% of pain in the low back. While examination shows motor weakness at 3/5, there is no myotomal deficit. Furthermore, MRI does not show a clear evidence of nerve root potential lesion. Finally, the patient did have an ESI on 10/14/14 with some reduction of pain. However, there is no evidence that the patient experience 50% or more reduction of pain lasting more than 6 weeks with associated reduction of medication. The patient's Morphine remained the same at 30mg dosage. The request IS NOT medically necessary.