MAXIMUS Federal Services

Case Number:	CM14-0106702		
Date Assigned:	08/06/2014	Date of Injury:	05/12/2012
Decision Date:	09/26/2014	UR Denial Date:	06/18/2014
Priority:	Standard	Application Received:	07/10/2014

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. The expert reviewer is Board Certified in Physical Medicine & Rehabilitation, Pain Medicine and is licensed to practice in Texas and Oklahoma. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 38-year-old male, who reported an injury on 05/10/2012; when he was reaching above his head while on a ladder, he lost his grip and fell. He fractured his left leg in 3 places. Diagnoses were low back pain, lumbar spine sprain/strain, lumbar spine degenerative disc disease, lumbar spine spondylosis, rule out lumbar radiculopathy, status post left knee arthroscopy with residual pain, left knee internal derangement, left ankle sprain/strain rule out derangement, irritable bowel syndrome, anxiety disorder, mood disorder, sleep disorder, stress, psychosexual dysfunction. Past treatments were physical therapy and acupuncture. Diagnostic studies were MRI of the left knee, MRI of the low back. Surgical history was left leg fracture repair, left knee surgery. Physical examination on 07/25/2014 revealed complaints of sharp, stabbing low back pain. The injured worker rated the pain at a 6/10 to 7/10 on the pain scale. He described the pain as frequent and constant, moderate to severe. It was also reported that the pain aggravated activities of daily living. It was also reported the injured worker was frustrated by the injury; he was experiencing stress, anxiety, insomnia, and depression brought on by chronic pain, physical limitations, inability to work, and uncertain future since the injury. The injured worker reported that medications offer him temporary relief of pain and improve his ability for a restful sleep. Examination of the lumbar spine revealed bilateral paraspinal muscle guarding. There was also tenderness to palpation on the quadratus lumborum muscle and spinous processes, L3-5. Range of motion for flexion was to 25 degrees; extension was to 15 degrees; left lateral flexion was to 10 degrees; right lateral flexion was to 7 degrees. Straight leg raise was positive at 60 degrees bilaterally. Kemp's test was positive bilaterally. Examination of the left knee revealed tenderness to palpation over the medial and lateral joint line and the patellofemoral joint. Range of motion for the left knee for flexion was to 95 degrees; extension was to -7 degrees. McMurray's test was positive on the left. Sensory examination revealed

slightly decreased sensation to pinprick and light touch at the L4, L5, and S1 dermatomes bilaterally. Deep tendon reflexes were 2+ and symmetrically in the bilateral lower extremities. Medications were Deprazine, Dicopanol, Fanatrex, Synapryn, Tabradol, cyclobenzaprine, ketoprofen cream. The rationale was submitted. The Request for Authorization was not submitted for review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 20 % in PLO gel: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics,Ketoprofen,Topical Muscle Relaxants,Cyclobenzaprine Page(s): 111,113,113,41.

Decision rationale: The California MTUS Guidelines indicate that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety and any compounded product that contains at least 1 drug (or drug class) that is not recommended, is not recommended, and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Ketoprofen is not currently FDA approved for a topical application. This medication also contains cyclobenzaprine, which is a muscle relaxant. The guidelines do not recommend the topical use of cyclobenzaprine as a topical muscle relaxant, as there is no evidence for use of any other muscle relaxant as a topical product. The medical guidelines do not support the use of ketoprofen. Therefore, the request for Ketoprofen 20 % in PLO gel is not medically necessary and appropriate.

Cyclophene 5% in PLO gel: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesic,Topical Muscle Relaxants, Cyclobenzaprine Page(s): 111,113,41.

Decision rationale: The California MTUS Guidelines indicate that topical analgesics are experimental in use with few randomized control trials to determine efficacy or safety, and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended, is not recommended. The guidelines do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxant, as there is no evidence for use of any other muscle relaxant as a topical product. The medical guidelines do not support the use of Cyclobenzaprine as a topical analgesic. Also, the request does not indicate a frequency for the medication. Therefore, the request for Cyclophene 5% in PLO gel is not medically necessary and appropriate.

Dicopanol 5 mg/ml Oral Suspension 150ml: 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 Official Disability Guidelines (ODG) Mental Illness and Stress, Insomnia Treatment.

Decision rationale: This medication is an antihistamine. The Official Disability Guidelines (ODG) state sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine or Benadryl). Tolerance seems to develop within a few days. Next day sedation has been noted as well as impaired psychomotor and cognitive function. This medication can be purchased over the counter. The efficacy of this medication was not reported. Also, the request does not indicate a frequency for this medication. Therefore, the request for Dicopanol 5 mg/ml Oral Suspension 150 ml is not medically necessary and appropriate.

Deprizine 5 mg/ml Oral Suspension 250ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 68,69.

Decision rationale: The request for Deprizine 5 mg/ml Oral Suspension 250 ml is non-certified. This medication is a compound of ranitidine hydrochloride oral suspension (Zantac). The California Medical Treatment Utilization Schedule states for proton pump inhibitors that the patient should be at immediate risk for gastrointestinal events and no cardiovascular disease; a nonselective NSAID with either a proton pump inhibitor or a Cox 2 selective agent should be given. Long term proton pump inhibitor use greater than 1 year has been shown to increase the risk of hip fracture. For patients at high risk for gastrointestinal events with no cardiovascular disease, a Cox 2 selective agent plus a proton pump inhibitor are recommended if absolutely necessary. It was not reported why the injured worker is on an oral suspension. Ranitidine can be purchased over the counter in a pill form. The medical necessity for this medication was not reported. Also, the request does not indicate a frequency for the medication. Therefore, the request is non-certified.

Fanatrex 25 mg/ml Oral Suspension 500 ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 16.

Decision rationale: This medication is an oral suspension of gabapentin. The California Medical Treatment Utilization Schedule states that gabapentin is shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first line treatment for neuropathic pain. The efficacy of this medication was not reported. It was not reported why the injured worker needs an oral suspension medication. Also, the request does not indicate a frequency for the medication. Therefore, the request is non-certified.

Synapryn 10mg/ml Oral Suspension 500 ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol, Ongoing Management Page(s): 82,93,94,113,78.

Decision rationale: This medication is an oral suspension form of Tramadol. The California Medical Treatment Utilization Schedule states central analgesic drugs such as tramadol (Ultram) are reported to be effective in managing neuropathic pain, and it is not recommended as a first line oral analgesic. The medical guidelines recommend that there should be documentation of the 4 A's for ongoing monitoring, including analgesia, activities of daily living, adverse side effects, and aberrant drug taking behavior. It was not reported why the injured worker needed to be on an oral suspension medication. The efficacy of this medication was not reported. Also, the request does not indicate a frequency for the medication. Therefore, the request for Synapryn 10mg/ml Oral Suspension 500 ml is not medically necessary and appropriate.

Tabradol 1mg/ml Oral Suspension 250 ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63.

Decision rationale: This medication is an oral suspension of Cyclobenzaprine, which is a muscle relaxant. The California Medical Treatment Utilization Schedule Guidelines recommend muscle relaxants as a second line option for the short term treatment of acute low back pain, and their use is recommended for less than 3 weeks. There should be documentation of objective functional improvement. The clinical documentation submitted for review does provide evidence that the patient has been on this medication for an extended duration of time, and there is a lack of documentation of objective improvement. Therefore, continued use of this medication would not be supported. Therefore, the request for Tabradol 1mg/ml Oral Suspension 250 ml is not medically necessary and appropriate.

1 Large LSO Lumbar Spine Brace: Overturned

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 298,301.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 300. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back Pain, Lumbar Supports.

Decision rationale: ACOEM states lumbar supports are not recommended for prevention. They are recommended as an option for treatment. They are recommended for compression fractures and specific treatment of spondylolisthesis, documented instability, and for treatment of nonspecific low back pain (very low quality evidence, but may be a conservative option). The ODG states they are also for the treatment of nonspecific low back pain, compared with no lumbar support, and elastic lumbar belt may be more effective than no belt at improving pain (measured by visual analog scale) and at improving functional capacity. However, evidence is weak (very low quality evidence). The injured worker had decrease in range of motion, positive nerve root tension and positive specialty tests. He does have complaints of low back pain. This is considered conservative care. Therefore, the request for one Large LSO lumbar spine brace is medically necessary and appropriate.

6 LINT Treatments for Lumbar Spine: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 298.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back Pain, Localized High-Intebsity Neurostimulation, Hyperstimulation Analgesia.

Decision rationale: This procedure is called localized high intensity neurostimulation. The Official Disability Guidelines state it is not recommended until there are higher quality studies. Initial results are promising, but only from two low quality studies sponsored by the manufacturer. Localized manual high intensity neurostimulation devices are applied to small surface areas to stimulate peripheral nerve endings, thus causing the release of endogenous endorphins. This procedure, usually described as hyperstimulation analgesia, has been investigated in several controlled studies. However, such treatments are time consuming and cumbersome and require previous knowledge of the localization of peripheral nerve endings responsible for low back pain or manual impedance mapping of the back, and these limitiations prevent their extensive utilization. The medical guidelines do not support the treatment of localized high intensity neurostimulation. Therefore, the request for six LINT treatments for lumbar spine is not medically necessary and appropriate.

Unknown Prescription Terocin Patches: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin/Lidocaine, topical.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics,Lidocaine Page(s): 111,112.

Decision rationale: The request for Unknown Prescription Terocin Patches is non-certified. The California Medical Treatment Utilization Guidelines indicate that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug (or drug class) that is not recommended, is not recommended. The guidelines indicate that topical lidocaine (Lidoderm) may be recommended for localized peripheral pain after there has been evidence of a trial of first line therapy (tricyclic or SNRI antidepressant or an AED such as gabapentin or Lyrica). No other commercially approved topical formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. The guidelines recommend treatment with topical salicylates. Per dailymed.nlm.nih.gov, Terocin patches are topical lidocaine and menthol. The medical guidelines do not support the use of compounded topical analgesics. Therefore, the request is non-certified.

Urine Drug Screen: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Official Disability Guidelines (ODG) Pain - Monitor Compliance with Prescribed Meds.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Ongoing Management Page(s): 78.

Decision rationale: The California Medical Treatment Utilization Schedule indicates that the use of urine drug screening is for patients with documented issues of abuse, addiction, or poor pain control. It was not reported that there were any apparent drug taking behaviors. Therefore, the request for a Urine Drug Screen is not medically necessary and appropriate.