

Case Number:	CM15-0204603		
Date Assigned:	10/21/2015	Date of Injury:	03/02/2001
Decision Date:	12/28/2015	UR Denial Date:	09/24/2015
Priority:	Standard	Application Received:	10/19/2015

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, Pain Management

CLINICAL CASE SUMMARY

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

This injured worker is a 58 year old male, who sustained an industrial injury on 03-01-2001. The injured worker was diagnosed as having status post anterior cervical decompression and fusion at C4-C6 in 2006 with residual, cervical spine musculoligamentous sprain-strain - rule out herniated nucleus pulposus, possible pseudoarthrosis of C4 through C6, bilateral upper extremity radiculopathy, lumbar spine musculoligamentous sprain-strain- rule out herniated nucleus pulposus, bilateral lower extremity radiculopathy, bilateral wrist musculoligamentous sprain-strain and bilateral shoulder musculoligamentous sprain-strain. On medical records dated 09- 01- 2015, the subjective complaints were noted as cervical spine pain. Bilateral shoulder pain that radiates to his arms, bilateral arm pain that radiates to hands was noted. Bilateral wrist-hand pain that radiates to fingers and lumbar spine lower back pain that radiates to bilateral lower extremities. Pain was rated 6-9 and noted that medication helps alleviated pain. Objective findings were noted as cervical spine revealed tenderness to palpation over the cervical paravertebral musculature, and a decreased range of motion. Bilateral shoulders revealed tenderness to palpation over the bilateral shoulder and decreased range of motion was noted. Bilateral wrists were noted as tenderness upon palpation over the bilateral wrists with a decreased range of motion. Lumbar spine revealed moderate tenderness to palpation over the lumbar paravertebral musculature with range of motion was decreased. Treatments to date included medication and physical therapy. The injured worker was noted to be not working Current medications were listed as Celebrex, Lyric, Sulindac, Clonazepam and Gabapentin. The Utilization Review (UR) was dated 09-24-2015. A Request for Authorization was dated 09-01-

2015. The UR submitted for this medical review indicated that the request for final confirmation of urine drug test results, lumbar pneumatic brace, X-force stimulator, Gabapentin 10%, Cyclobenzaprine 10%, Capsaicin 0.0375% cream 120 grams and Ketoprofen 20%, Ketamine 10% Cream 120grams was non-certified.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 20%, Ketamine 10% Cream 120grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: The Chronic Pain Medical Treatment Guidelines on page 112 state the following: "Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol, 1996). Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. (Krummel 2000)" Within the submitted documentation, there is no explanation as to why the topical ketoprofen is prescribed despite MTUS recommendations against this formulation. It is not apparent if the worker has failed other forms of topical NSAIDs recommended by the CPMTG. Given this, this request is not medically necessary.

Gabapentin 10%, Cyclobenzaprine 10%, Capsaicin 0.0375% cream 120 grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: With regard to this request for a topical compounded cream that contains gabapentin as a component, the CPMTG does not recommend topical gabapentin. On page 113 of the Chronic Pain Medical Treatment Guidelines, the following is stated: "Gabapentin: Not recommended. There is no peer-reviewed literature to support use." The guidelines further state that if one drug or drug class of a compounded formulation is not recommended, then the entire compounded formulation is not recommended. Therefore, the topical gabapentin component is not recommended, and the entire formulation is not medically necessary.

1 X-force Stimulator: Upheld

Claims Administrator guideline: Decision based on MTUS Low Back Complaints 2004.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Transcutaneous electrotherapy.

Decision rationale: With regard to the request for an X-force Stimulator, the CA MTUS, ACOEM, and ODG do not have guidelines on this device. The manufacturer's website has stated the following: "The X-Force Stimulator is a proprietary device that utilizes a unique electrical signal to deliver monophasic, peaked impulses directly to the joint. The device is a dual modality unit, offering TEJS and TENS functions that both use electrical stimulation to combat pain found in the joint capsule. The FDA has approved the X-Force Stimulator and has classified the device with a product code of NYN. This is important as conventional TENS units are classified by the FDA using the product code GZJ. Thus, the X-Force Stimulator is inherently unique from TENS units and other electrical stimulation devices, and is recognized as such." In this case, it does not appear that the patient has tried more conventional forms of transcutaneous electric stimulation. A more conventional unit would be appropriate given the guideline support for some other units such as conventional TENS, IF, or other devices. There is a lack of evidenced based studies to support this device and it is not medically necessary.

1 Kronos Lumbar Pneumatic Brace: Upheld

Claims Administrator guideline: Decision based on MTUS Low Back Complaints 2004.

MAXIMUS guideline: Decision based on MTUS Low Back Complaints 2004, Section(s): Physical Methods. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back Chapter, Lumbar Supports.

Decision rationale: Regarding the request for this pneumatic back brace, ACOEM guidelines state that lumbar supports have not been shown to have any lasting benefit beyond the acute phase of symptom relief. ODG states that lumbar supports are not recommended for prevention. They go on to state the lumbar support are recommended as an option for compression fractures and specific treatment of spondylolisthesis, documented instability, and for treatment of nonspecific low back pain. ODG goes on to state that for nonspecific low back pain, compared to no lumbar support, elastic lumbar belt maybe more effective than no belt at improving pain at 30 and 90 days in people with subacute low back pain lasting 1 to 3 months. However, the evidence was very weak and thus supports are not necessary for this indication. Within the documentation available for review, it does not appear that this patient is in the acute or subacute phase of his treatment. Additionally, there is no documentation indicating that the patient has a diagnosis of compression fracture, spondylolisthesis, or instability. In the case of this request for back brace, evidence-based guidelines do not recommend lumbar bracing in general. There is a paucity of evidence to recommend lumbar bracing for the treatment or prevention of low back pain. As such, the currently requested lumbosacral orthosis is not medically necessary.

1 Final Confirmation of Urine Drug Test results: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, steps to avoid misuse/addiction.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Drug testing, Opioids, dealing with misuse & addiction, Opioids, steps to avoid misuse/addiction. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain Chapter, Urine Drug Testing.

Decision rationale: Regarding the request for a urine toxicology test, CA MTUS Chronic Pain Medical Treatment Guidelines state the drug testing is recommended as an option in patients on controlled substances. Guidelines go on to recommend monitoring for the occurrence of any potentially aberrant (or non-adherent) drug related behaviors. ODG recommends urine drug testing on a yearly basis for low risk patients, 2-3 times a year for moderate risk patients, and possibly once per month for high risk patients. Risk stratification is an important component in assessing the necessity and frequency of urine drug testing. With the documentation available for review, there is documentation of prescription of controlled substances such as clonazepam. A progress note on 9/1/15 requests a confirmation test which would involve sending out the specimen to a laboratory. However, the documentation does not make clear whether a urine screening test such as RIA was done in the office. Typically this is a screening test, and when results are unexpected, then a confirmation is necessary. In this case, there is no commentary as to what type of screening test was done and the results of any such test. This point needs to be clarified before a toxicology confirmation should be performed. Given this, this request is not medically necessary.