

<b>Case Number:</b>	CM15-0093586		
<b>Date Assigned:</b>	05/21/2015	<b>Date of Injury:</b>	03/18/2014
<b>Decision Date:</b>	10/07/2015	<b>UR Denial Date:</b>	05/01/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/14/2015

### 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: Preventive Medicine, Occupational Medicine

### 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 34 year old male, who sustained an industrial injury on 2/18/2014. He reported a slip and fall causing low back pain with radiation into the right leg. Diagnoses include lumbar sprain, lumbago, disc herniation, radiculopathy, bilateral knee internal derangement, bilateral ankle sprain and respiratory problems. Treatments to date include NSAID, analgesic, muscle relaxants, rest, physical therapy, acupuncture, and trigger point injections. Currently, he complained of burning radicular low back pain and muscle spasms. The pain was rated 6/10 VAS. He also complained of bilateral knee and ankle pain, both rated 6/10 VAS. On 4/29/15, the physical examination documented decreased range of motion and tenderness. There was decreased sensation to bilateral low extremities noted. The knees and ankles were also noted to have mild decreased range of motion. The plan of care included Ketoprofen 20% topical cream, Cyclobenzaprine 5% topical cream, Synapryn 110gm/1ml, 500ml; Tabradol 1mg/ml 250ml; Deprizine 15mg/ml 250ml; Dicopanol 5mg/ml 150ml; Fanatrex 25mg/ml 420ml; Urine analysis toxicology evaluation; Terocin patches; one x-ray of the lumbar spine; one MRI of the lumbar spine; six sessions of shockwave therapy; six localized intense neurostimulation therapy (LINT) sessions; one functional capacity evaluation; and one Lumbar Support Orthotic (LSO) back brace.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ketoprofen 20% cream 167gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

**Decision rationale:** According to the MTUS, there is little to no research to support the use of many of these compounded topical analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Ketoprofen agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. Ketoprofen 20% cream 167gm is not medically necessary.

**Cyclobenzaprine 5% cream 110gms:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

**Decision rationale:** According to the MTUS, there is little to no research to support the use of many of these compounded topical analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. There is no evidence for use of any muscle relaxant as a topical product. Cyclobenzaprine 5% cream 110gms is not medically necessary.

**Synapryn 110gm/1ml 500ml:** 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) Pain (Chronic), Compound drugs.

**Decision rationale:** The requested compound medication contains unnamed and then defined "other proprietary ingredients". In addition, there is no documentation that the patient has a contraindication to medication prescribed in tablet form. According to the Official Disability Guidelines, compounded drugs are not recommended as a first-line therapy. In general, commercially available, FDA-approved drugs should be given an adequate trial. If these are found to be ineffective or are contraindicated in individual patients, compound drugs that use FDA-approved ingredients may be considered. There is no documentation that

the FDA approved medication was given an adequate trial. Synapryn 110gm/1ml 500ml is not medically necessary.

**Tabradol 1mg/ml 250ml:** 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) Pain (Chronic), Compound drugs.

**Decision rationale:** The requested compound medication contains unnamed and then defined "other proprietary ingredients". In addition, there is no documentation that the patient has a contraindication to medication prescribed in tablet form. According to the Official Disability Guidelines, compounded drugs are not recommended as a first-line therapy. In general, commercially available, FDA-approved drugs should be given an adequate trial. If these are found to be ineffective or are contraindicated in individual patients, compound drugs that use FDA-approved ingredients may be considered. There is no documentation that the FDA approved medication was given an adequate trial. Tabradol 1mg/ml 250ml is not medically necessary.

**Deprizine 15mg/ml 250ml:** 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) Pain (Chronic), Compound drugs.

**Decision rationale:** The requested compound medication contains unnamed and then defined "other proprietary ingredients". In addition, there is no documentation that the patient has a contraindication to medication prescribed in tablet form. According to the Official Disability Guidelines, compounded drugs are not recommended as a first-line therapy. In general, commercially available, FDA-approved drugs should be given an adequate trial. If these are found to be ineffective or are contraindicated in individual patients, compound drugs that use FDA-approved ingredients may be considered. There is no documentation that the FDA approved medication was given an adequate trial. Deprizine 15mg/ml 250ml is not medically necessary.

**Dicopanol 5mg/ml 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) Pain (Chronic), Compound drugs.

**Decision rationale:** The requested compound medication contains unnamed and then defined "other proprietary ingredients". In addition, there is no documentation that the patient has a contraindication to medication prescribed in tablet form. According to the Official Disability Guidelines, compounded drugs are not recommended as a first-line therapy. In general, commercially available, FDA-approved drugs should be given an adequate trial. If these are found to be ineffective or are contraindicated in individual patients, compound drugs that use FDA-approved ingredients may be considered. There is no documentation that the FDA approved medication was given an adequate trial. Dicopanol 5mg/ml 150ml is not medically necessary.

**Fanatrex 25mg/ml 420ml:** 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) Pain (Chronic), Compound drugs.

**Decision rationale:** The requested compound medication contains unnamed and then defined "other proprietary ingredients". In addition, there is no documentation that the patient has a contraindication to medication prescribed in tablet form. According to the Official Disability Guidelines, compounded drugs are not recommended as a first-line therapy. In general, commercially available, FDA-approved drugs should be given an adequate trial. If these are found to be ineffective or are contraindicated in individual patients, compound drugs that use FDA-approved ingredients may be considered. There is no documentation that the FDA approved medication was given an adequate trial. Fanatrex 25mg/ml 420ml is not medically necessary.

**Periodic UA Toxicological Evaluation:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic), Urine Drug Testing (UDT).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Drug testing.

**Decision rationale:** The MTUS recommends using a urine drug screen to assess for the use or the presence of illegal drugs, a step to take before a therapeutic trial of opioids, to aid in the ongoing management of opioids, or to detect dependence and addiction. There is no documentation in the medical record that a urine drug screen was to be used for any of the above indications. Periodic UA Toxicological Evaluation is not medically necessary.

**Unknown prescription of Terocin patches: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

**Decision rationale:** According to the MTUS, compounds containing lidocaine are not recommended for non-neuropathic pain. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. The patient's physical exam shows no evidence of radiculopathy or neuropathic pain. In addition, there is little to no research to support the use of many of these Compounded Topical Analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Unknown prescription of Terocin patches are not medically necessary.

**X-rays of the Lumbar Spine is not: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Low Back Complaints 2004, Section(s): Summary.

**Decision rationale:** The MTUS states that radiographs of the lumbar spine are indicated when red flags are present indicating fracture, cancer, or infection. The medical record contains no documentation of red flags indicating that a lumbar x-ray is indicated. At present, based on the records provided, and the evidence-based guideline review, the request for X-rays of the Lumbar Spine is not medically necessary.

**MRI of the Lumbar Spine: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Low Back Complaints 2004. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back, Lumbar and Thoracic (Acute & Chronic), MRIs.

**MAXIMUS guideline:** Decision based on MTUS Low Back Complaints 2004, Section(s): Special Studies.

**Decision rationale:** The MTUS states that unequivocal objective findings that identify specific nerve compromise on the neurologic examination are sufficient evidence to warrant imaging in patients who do not respond to treatment and who would consider surgery an option. When the neurologic examination is less clear, however, further physiologic evidence of nerve dysfunction should be obtained before ordering an imaging study. Indiscriminant imaging will result in false-positive findings, such as disk bulges, that are not the source of painful symptoms and do not warrant surgery. The medical record fails to document sufficient findings indicative of nerve root

compromise which would warrant an MRI of the lumbar spine. MRI of the Lumbar Spine is not medically necessary.

#### **6 sessions of Shockwave Therapy for the Lumbar Spine: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back, Lumbar and Thoracic (Acute & Chronic), Shockwave therapy.

**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 - Lumbar & Thoracic (Acute & Chronic), Shock wave therapy.

**Decision rationale:** The Official Disability Guidelines do not recommend shockwave therapy. The available evidence does not support the effectiveness of ultrasound or shock wave for treating LBP. In the absence of such evidence, the clinical use of these forms of treatment is not justified and should be discouraged. Limited evidence exists regarding extracorporeal shock wave therapy (ESWT) in reducing pain and improving function. While it appears to be safe, there is disagreement as to its efficacy. Insufficient high quality scientific evidence exists to determine clearly the effectiveness of this therapy. 6 sessions of Shockwave Therapy for the Lumbar Spine is not medically necessary.

#### **6 sessions of Localized Intense Neurostimulation Therapy (LINT): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back, Lumbar & Thoracic (Acute & Chronic), Localized high-intensity nerve stimulation.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Percutaneous electrical nerve stimulation (PENS).

**Decision rationale:** There is no documentation that LINT is to be used as an adjunct to a program of evidence-based functional restoration, after other non-surgical treatments, including therapeutic exercise and TENS, have been tried and failed or are judged to be unsuitable or contraindicated. 6 sessions of Localized Intense Neurostimulation Therapy (LINT) is not medically necessary.

#### **Functional Capacity Evaluation: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Fitness for Duty, Functional Capacity Evaluation (FCE).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Fitness For Duty, Functional capacity evaluation (FCE).

**Decision rationale:** The Official Disability Guidelines state that a functional capacity evaluation is appropriate if, case management is hampered by complex issues, and the timing is appropriate; such as if the patient is close to being at maximum medical improvement or additional clarification concerning the patient's functional capacity is needed. Functional capacity evaluations are not needed if the sole purpose is to determine a worker's effort or compliance, or the worker has returned to work. There is no documentation in the medical record to support a functional capacity evaluation based on the above criteria. Functional Capacity Evaluation is not medically necessary.

**LSO 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 rationale:** According to the MTUS, lumbar supports have not been shown to have any lasting benefit beyond the acute phase of symptom relief. Based on the patient's stated date of injury, the acute phase of the injury has passed. LSO brace is not medically necessary.