

<b>Case Number:</b>	CM15-0071701		
<b>Date Assigned:</b>	04/27/2015	<b>Date of Injury:</b>	10/13/2014
<b>Decision Date:</b>	09/22/2015	<b>UR Denial Date:</b>	03/24/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/14/2015

### 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:

This 57 year old male sustained an industrial injury on 10/13/14. He subsequently reported low back and right knee injury and pain. Diagnoses include low back pain, radiculitis lower extremity and rule out lumbar disc displacement HNP. The plan of treatment include x-ray and MRI testing, an LSO brace, cane and TENS unit. The injured worker continues to experience low back pain with radiation to bilateral lower extremities and right knee pain. Pain is rated at 7-9 on a scale of 10. A request for Shockwave therapy, acupuncture, physical therapy and Depizine, Dicopanol, Fanatrx, Synapryn, Tabradol, Cyclobenzaprine, Ketoprofen and Terocin medications was made by the treating physician.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Deprizine quantity and duration unspecified:** Upheld

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

**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 quantity and duration unspecified is not medically necessary.

**Dicopanol quantity and duration unspecified:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**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 quantity and duration unspecified is not medically necessary.

**Fanatrex quantity and duration unspecified:** Upheld

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

**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 quantity and duration unspecified is not medically necessary.

**Synapryn quantity and duration unspecified:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [dailymed.nlm.nih.gov/dailymed/druginfo.cfm?id=20039](https://dailymed.nlm.nih.gov/dailymed/druginfo.cfm?id=20039).

**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 quantity and duration unspecified is not medically necessary.

**Tabradol quantity and duration unspecified:** Upheld

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

**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 quantity and duration unspecified is not medically necessary.

**Cyclobenzaprine quantity and duration unspecified:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 9792.20 - 9792.26 Page(s): 64.

**Decision rationale:** The Chronic Pain Treatment Guidelines do not recommend long-term use of muscle relaxants. There are no muscle spasms documented on the physical exam. There is no documented functional improvement from any previous use in this patient. The MTUS also state that muscle relaxants are no more effective than NSAID's alone. Based on the currently available information, the medical necessity for this muscle relaxant medication has not been established. Cyclobenzaprine quantity and duration unspecified is not medically necessary.

**Ketoprofen cream quantity and duration unspecified:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 9792.20 - 9792.26 Page(s): 112.

**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 cream quantity and duration unspecified is not medically necessary.

**Shockwave therapy:** 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) Lumbar & Thoracic (Acute & Chronic), Extracorporeal shock wave therapy (ESWT).

**Decision rationale:** According to the Official Disability Guidelines, 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. Shockwave therapy is not medically necessary.

**Acupuncture three times a week for six weeks for the lumbar spine:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Acupuncture Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Acupuncture Treatment Guidelines.

**Decision rationale:** The Acupuncture Medical Treatment Guidelines state that the initial authorization for acupuncture is for 3-6 treatments. Authorization for more than 6 treatments would be predicated upon documentation of functional improvement. The request for 18 treatments is greater than the number recommended for a trial to determine efficacy. Acupuncture three times a week for six weeks for the lumbar spine is not medically necessary.

**Physical therapy three times a week for the lumbar spine:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 9792.20 - 9792.26 Page(s): 58-60.

**Decision rationale:** The MTUS allows for fading of treatment frequency (from up to 3 visits per week to 1 or less), plus active self-directed home Physical Medicine. Prior to full authorization, therapeutic physical therapy is authorized for trial of 6 visits over 2 weeks, with evidence of objective functional improvement prior to authorizing more treatments. There is no documentation of objective functional improvement and the request is for greater than the number of visits necessary for a trial to show evidence of objective functional improvement prior to authorizing more treatments. Physical therapy three times a week for the lumbar spine is not medically necessary.

**Terocin patches:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 9792.20 - 9792.26 Page(s): 111-112.

**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. Terocin patches are not medically necessary.