

<b>Case Number:</b>	CM14-0081371		
<b>Date Assigned:</b>	08/08/2014	<b>Date of Injury:</b>	08/23/2012
<b>Decision Date:</b>	09/30/2014	<b>UR Denial Date:</b>	05/09/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/02/2014

### 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, has a subspecialty in Pain Medicine and is licensed to practice in Texas and Ohio. 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 37-year-old male who reported an injury on 08/23/2012 due to cumulative trauma-type injuries. The injured worker complained of neck and left shoulder pain along with mid back and lower back. The diagnoses included cervical spine HNP, cervical radiculopathy, left shoulder rotator cuff tear, left shoulder tendinitis, thoracic spine sprain/strain, thoracic spine pain, lower back pain, lumbar HNP, and lumbar spine radiculopathy. The MRI of the lumbar spine dated 02/05/2014 revealed degenerative disc disease at the L3-4, L4-5, and L5-S1; prominent fatty endplate marrow; multiple Schmorl's nodes. The MRI of the cervical spine dated 02/04/2013 revealed focal disc protrusions at C3-4, facet arthropathy at C4-5, and focal disc protrusion at C5-6. The past diagnostics included an electromyography and nerve conduction study. The past treatments included physical therapy, TENS unit, medication, and lumbar injections. The medications included Deprizine, Dicoprofanol, Fanatrex, Synapryn, Tabradol, flurbiprofen, capsaicin, tramadol, menthol, and cyclobenzaprine. The physical examination of the cervical spine dated 04/25/2014 revealed tenderness to palpation over the suboccipital muscles and over the sternocleidomastoid muscle. The range of motion with flexion was at 35 degrees and extension 30 degrees. The physical examination of the left shoulder revealed tenderness to palpation over the AC joint, subacromial space, and at the supraspinatus muscle with flexion 115 degrees and extension 20 degrees. The physical examination of the lumbar spine revealed tenderness to palpation to the bilateral paraspinal. Positive straight leg raise; reflexes were 2+; deep tendon reflexes 2+. Motor strength to the myotomes were decreased bilaterally at L2, L3, L4, and S1. Treatment plan included the use of medication, approval for ENT specialist, continue with neurostimulation therapy, and chiropractic treatment. The request for authorization dated 03/21/2014 was submitted within the documentation.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**ENT Evaluation per sleep study recommendation:** 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).

**Decision rationale:** The Official Disability Guidelines indicate that the injured worker meet the following criteria. Polysomnograms / sleep studies are recommended for the combination of indications listed below. Excessive daytime somnolence, Cataplexy (muscular weakness usually brought on by excitement or emotion, virtually unique to narcolepsy, Morning headache (other causes have been ruled out), Intellectual deterioration (sudden, without suspicion of organic dementia), Personality change (not secondary to medication, cerebral mass or known psychiatric problems); Sleep-related breathing disorder or periodic limb movement disorder is suspected; & Insomnia complaint for at least six months (at least four nights of the week), unresponsive to behavior intervention and sedative/sleep-promoting medications and psychiatric etiology has been excluded. A sleep study for the sole complaint of snoring, without one of the above mentioned symptoms, is not recommended. The clinical notes were not evident that the injured worker met the above criteria. As such, the request is not medically necessary.

**Terocin patches (dosage and quantity not indicated):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Salicylate, Topical Analgesic, Lidocaine Page(s): 105, 111, 112.

**Decision rationale:** The California MTUS indicates that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety 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 California MTUS 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 (tri-cyclic or SNRI anti-depressants 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. California MTUS guidelines recommend treatment with topical salicylates. Per [dailymed.nlm.nih.gov](http://dailymed.nlm.nih.gov), Terocin patches are topical Lidocaine and Menthol. The request did not address the dosage and quantity. As such, the request is not medically necessary.

**Deprizine (dosage and quantity not indicated): 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, does not specifically address Deprizine Page(s): 69.

**Decision rationale:** The California MTUS Guidelines recommends Histamine 2 blockers for treatment of dyspepsia secondary to NSAID therapy. The medication Deprizine includes ranitidine, which is a Histamine 2 blocker and can be used for the treatment of dyspepsia. However, per Drugs.com, Deprizine: Generic Name: ranitidine hydrochloride has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. The request did not indicate the frequency or dosage or duration. As such, the request is not medically necessary.

**Dicopanol (dosage and quantity not indicated): 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 ANTISPASMODICS Page(s): 64.

**Decision rationale:** This drug is similar to diphenhydramine, but has greater anticholinergic effects. The mode of action is not clearly understood. Effects are thought to be secondary to analgesic and anticholinergic properties. This drug was approved by the FDA in 1959. The request did not address the dosage and or frequency. As such, the request is not medically necessary.

**Fanatrex (dosage and quantity not indicated): 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 Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/search.php?searchterm=Fanatre>.

**Decision rationale:** The California MTUS Guidelines recommend tramadol for pain; however, do not recommend it as a first-line oral analgesic. California MTUS guidelines recommend Glucosamine Sulfate for patients with moderate arthritis pain especially, knee osteoarthritis and that only one medication should be given at a time. Synapryn per the online package insert included tramadol and glucosamine sulfate. Clinical documentation submitted for review failed to provide the necessity for an oral suspension which included tramadol and glucosamine sulfate.

There should be documentation of an objective improvement in function, an objective decrease in pain, and evidence that the patient is being monitored for aberrant drug behavior and side effects. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. Clinical documentation submitted for review failed to provide exceptional factors to warrant non-adherence to guideline recommendations. The request did not address the frequency, dosage, route or duration. As such, the request is not medically necessary.

**Synapryn (dosage and quantity not indicated): 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 Glucosamine Sulfate, Ongoing Management, Tramadol Page(s): 50, 78, 82, 93, 94.

**Decision rationale:** The request for Synapryn (dosage and quantity not indicated) is not medically necessary. The California MTUS Guidelines recommend tramadol for pain; however, do not recommend it as a first-line oral analgesic. California MTUS guidelines recommend Glucosamine Sulfate for patients with moderate arthritis pain especially, knee osteoarthritis and that only one medication should be given at a time. Synapryn per the online package insert included tramadol and glucosamine sulfate. Clinical documentation submitted for review failed to provide the necessity for an oral suspension which included tramadol and glucosamine sulfate. There should be documentation of an objective improvement in function, an objective decrease in pain, and evidence that the patient is being monitored for aberrant drug behavior and side effects. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. Clinical documentation submitted for review failed to provide exceptional factors to warrant non-adherence to guideline recommendations. The request did not address the frequency, dosage, route or duration. As such, the request is not medically necessary.

**Tabradol (dosage and quantity not indicated): 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 Cyclobenzaprine Page(s): 41.

**Decision rationale:** The California MTUS indicate that Cyclobenzaprine (Flexeril) is recommended for a short course of therapy. This medication is not recommended to be used for longer than 2-3 weeks. The addition of cyclobenzaprine to other agents is not recommended. They do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. Tabradol is a

compounding kit for oral suspension of cyclobenzaprine and methylsulfonylmethane. A search of ACOEM, California MTUS guidelines and Official Disability Guidelines, along with the National Guideline Clearinghouse (NCG) and the PubMed database returned no discussion on Tabradol. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. There was a lack of evidence based literature for the oral compounding of cyclobenzaprine and methylsulfonylmethane over the commercially available oral forms and the lack of medical necessity requiring an oral suspension of these medications. The request did not address the frequency, duration, route or dosage. As such, the request is not medically necessary.

**Flurbiprofen cream (dosage and quantity not indicated): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): page 111. Decision based on Non-MTUS Citation Official Disability Guidelines Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic pain, Flurbiprofen, Topical analgesics, Topical Capsaicin, Topical Salicylates Page(s): 72, 111, 28, 112, 105.

**Decision rationale:** The California MTUS indicates topical analgesics are experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. California MTUS guidelines recommend Topical Salicylates. Methyl Salicylate 4% is one of the ingredients of this compound. As the topical Flurbiprofen is not supported by the FDA or the treatment guidelines, the request is not medically necessary.

**Capsaicin Cream (dosage and quantity not indicated): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals, Topical Capsaicin, Topical Ketoprofen Page(s): 28, 112, 105.

**Decision rationale:** The California MTUS indicates Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety 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. Regarding the use of Ketoprofen: This agent is not currently FDA approved for a topical application, Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. The guidelines support the use of topical salicylates. The request did not address the dosage and quantity. As such, the request is not medically necessary.

**Tramadol (dosage and quantity not indicated):** 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:** The California MTUS states Central analgesics 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. California MTUS 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. The request did not address the frequency, dosage, duration or route. As such, the request is not medically necessary.

**Menthol topical (dosage and quantity not indicated):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical Salicylates, page 105, Topical Analgesics, page 111, Topical Capsaicin, page 28 Page(s): 105, 111, 28.

**Decision rationale:** The California MTUS indicates that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. California MTUS guidelines recommend treatment with topical salicylates. Drugs.com indicates Exoten C is a topical analgesic containing Methyl salicylate, Menthol and 0.02% capsaicin. The request did not address the frequency, duration, dosage or route. As such, the request is not medically necessary.

**Cyclobenzaprine (dosage and quantity not indicated): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines Muscle Relaxants - Flexeril.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41.

**Decision rationale:** The California MTUS indicate that Cyclobenzaprine (Flexeril ) is recommended for a short course of therapy. This medication is not recommended to be used for longer than 2-3 weeks. The addition of cyclobenzaprine to other agents is not recommended. They do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. Tabradol is a compounding kit for oral suspension of cyclobenzaprine and methylsulfonylmethane. A search of ACOEM, California MTUS guidelines and Official Disability Guidelines, along with the National Guideline Clearinghouse (NCG) and the PubMed database returned no discussion on Tabradol. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. There was a lack of evidence based literature for the oral compounding of cyclobenzaprine and methylsulfonylmethane over the commercially available oral forms and the lack of medical necessity requiring an oral suspension of these medications. The request did not address the frequency, duration, dosage or route (dosage and quantity not indicated). As such, the request is not medically necessary.