

<b>Case Number:</b>	CM15-0183245		
<b>Date Assigned:</b>	09/29/2015	<b>Date of Injury:</b>	09/06/2011
<b>Decision Date:</b>	12/02/2015	<b>UR Denial Date:</b>	08/25/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/17/2015

### 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: New York, California  
 Certification(s)/Specialty: Emergency 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 42 year old, male who sustained a work related injury on 9-6-11. A review of the medical records shows he is being treated for low back pain. Current medications include Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Cyclobenzaprine, and medicated topical creams. He has been taking these medications since at least 9-2014. There is insufficient documentation on previous courses of physical therapy and-or chiropractic treatments. In the progress notes over the last six to nine months, the injured worker reports burning low back pain. He rates his average pain level a 5-7 out of 10. He has pain associated with numbness and tingling in both legs. He states his symptoms "persist" but the medications do "offer him temporary relief of pain and improve his ability to have restful sleep." He states his pain is also alleviated by activity restrictions. On physical exam in report of 7-20-15, he has tenderness to palpation in lumbar paraspinal muscles and over the lumbosacral junction. He has decreased range of motion in lumbar spine. He has decreased sensation and motor strength in legs. He has positive straight leg raises in both legs. Documentation of working status not noted. The treatment plan includes continuing medications and courses of physical therapy and chiropractic therapy. In the Utilization Review dated 8-25-15, the requested treatments of Ketoprofen 20% and Cyclobenzaprine 5% creams, medications of Synapryn 10mg-ml 500ml, Tabradol 1mg-ml 250ml, Deprizine 15mg-ml 250ml, Dicopanol (Diphenhydramine) 5mg-ml 150ml and Fanatrex (Gabapentin) 25mg-ml 420ml and physical therapy and chiropractic therapy 3 x 6 for the lumbar spine have all been found not medically necessary.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Ketoprofen 20% cream 167 grams:** 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:** Ca MTUS guidelines for topical analgesic agents are referenced above. According to these guidelines, Ketoprofen is not currently FDA approved for topical application. This medication is known to have high incidence of photo-contact dermatitis. Additionally, there the request does not include location or frequency of application. As this medication is not supported by the guidelines or FDA approved, the request is determined not medically necessary.

**Cyclobenzaprine 5% cream 110 grams:** 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:** Ca MTUS guidelines for topical analgesic agents are referenced above. According to these guidelines, there is no evidence for use of any other muscle relaxant as a topical product. Additionally, there the request does not include location or frequency of application. As this medication is not supported by the guidelines or FDA approved, the request is determined not medically necessary.

**Synapryn 10mg/ml 500ml:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation  
<http://www.bioportfolio.com/resources/drug/22213/Synapryn.html>.

**Decision rationale:** Synapryn is a compounded substance that includes Tramadol as a primary ingredient and typically glucosamine as a second ingredient. While tramadol is discussed in CA MTUS, this compounded formulation is not. ODG is also silent on this substance. Tramadol is a synthetic opioid that is typically prescribed for as needed dosing for pain control. The indications specific to Tramadol are not apparent in chart documentation. The dosing, frequency and effects are not stated. Opioid medication is not supported for use in chronic back pain. The other

component, glucosamine, is recommended as an option for the treatment of moderate arthritic pain, mainly the knees. The IW does not have an active diagnosis of arthritis. The combination of these medications is not supported as one is intended for as needed breakthrough pain and carries substantial medical risks due to its potential accumulative effect. The other is for moderate pain caused by osteoarthritis and is used more liberally without the same toxicologic profile. The combination preparation is not supported and therefore, not medically necessary.

**Tabradol 1mg/ml 250ml:** 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): Cyclobenzaprine (Flexeril).

**Decision rationale:** Tabradol is cyclobenzaprine in an oral suspension. The MTUS for Chronic Pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short term exacerbations of chronic low back pain. This patient has chronic pain with no evidence of prescribing for flare-ups, and the pain is in the extremity, not the low back. The MTUS states that treatment with cyclobenzaprine should be brief, and that the addition of cyclobenzaprine to other agents is not recommended. In this case, cyclobenzaprine is added to other agents, and the oral suspension form plus topical is experimental and unproven. Prescribing was not for a short term exacerbation. Multiple medications, including a topical muscle relaxant, were prescribed together without adequate trials of each. Per the MTUS, cyclobenzaprine is not indicated and is not medically necessary.

**Deprizine 15mg/ml 250ml:** 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): NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** Deprizine is the oral solution equivalent of ranitidine. According to CA MTUS, gastrointestinal protecting agents are recommended for patients that are at increased risk for gastrointestinal events. These risks include age >65, history or gastrointestinal bleeding or peptic ulcers, concomitant use of NSAIDs and corticosteroids or aspirin, or high dose NSAID use. The chart does not document any of these risk factors. Past medical history does not include any gastrointestinal disorders, there is no history of poor tolerance to NSAIDs documented and there are not abdominal examinations noted in the chart. Ranitidine is not medically necessary based on the MTUS.

**Dicopanol (Diphenhydramine) 5mg/ml 150ml:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation. <http://www.drugs.com/pro/dicopanol.html>.

**Decision rationale:** According to the treating provider's documentation, Dicopanol is a combination of antihistamine and other proprietary ingredients. Unknown components of a medication cannot be evaluated to determine their safety or medical necessity. Additionally, the request does not include dosing or frequency. As such, the request for Dicopanol is not medically necessary.

**Fanatrex (gabapentin) 25mg/ml 420ml: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/fanatrex.html>.

**Decision rationale:** According to the above reference, Fanatrex is a combination of Gabapentin and other proprietary ingredients. Unknown components of a medication cannot be evaluated to determine their safety or medical necessity. According to CA MTUS, topical Gabapentin is not recommended as there is no peer reviewed literature to support its use. Additionally, the request does not include frequency or dosing. As such, the request for Fanatrex is not medically necessary.

**Physical Therapy 3x6 for the lumbar spine: 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): Physical Medicine.

**Decision rationale:** CA MTUS chronic pain guidelines for manual therapy and manipulation are used in support of this decision. It is assumed this request is for first time physical therapy evaluation and treatment. Documentation does not support the IW has previously undergone such treatments. According to referenced guidelines, manual therapies are recommended for musculoskeletal conditions. Guidelines support a trial of 6 visits over 2 weeks with evidence of functional improvements. The current request is for a trial of 3 visits over 6 weeks. The request for 18 visits exceeds the guideline recommendation. As such, the request for 3x6 physical therapy treatments is not medically necessary.

**Chiropractic therapy 3x6 for the lumbar spine: 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): Physical Medicine.

**Decision rationale:** CA MTUS chronic pain guidelines for manual therapy and manipulation are used in support of this decision. It is assumed this request is for ongoing chiropractic therapy as the submitted records include one chiropractic visit notes from June 2015. Documentation does not include the number of previous chiropractic therapy treatments or any measure of functional improvement resulting from these treatments. Other conservative treatments with the exception of medications are not included in the chart materials. The IW remains TTD and previous pain medications were renewed without any mention of decreasing dosing or frequency. Guidelines support a trial of 6 visits over 2 weeks with evidence of functional improvements. Following initial visits, the guidelines do not recommend maintenance appointments. The request for 18 visits exceeds this recommendation. As such, the request for 3x6 chiropractic treatments is not medically necessary.