

<b>Case Number:</b>	CM15-0101011		
<b>Date Assigned:</b>	06/03/2015	<b>Date of Injury:</b>	04/10/2014
<b>Decision Date:</b>	07/09/2015	<b>UR Denial Date:</b>	04/29/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/26/2015

### 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 Jersey, New York  
 Certification(s)/Specialty: Family Practice

### 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 43 year old male, who sustained an industrial injury on 4/10/14. He reported right shoulder and neck injury following a heavy part of a truck fell on him. The injured worker was diagnosed as having cervical spine sprain/strain, rule out cervical spine radiculopathy, bilateral shoulder sprain/strain, lumbar spine sprain/strain, rule out radiculitis of lower extremity and status post right ankle surgery with residual pain. Treatment to date has included surgical repair of right ankle/foot, oral medications, physical therapy, acupuncture, chiropractic treatment, shockwave therapy and topical medications. Currently, the injured worker complains of burning, radicular neck pain and muscle spasms rated 7/10 and associated with numbness and tingling of the bilateral upper extremities; burning bilateral shoulder pain radiating down the arms to the fingers associated with muscle spasms rated 7/10 and burning, radicular low back pain and muscle spasms rated 6/10 and associated with numbness and tingling of the bilateral lower extremities. Physical exam noted tenderness to palpation at the occiputs, trapezius, sternocleidomastoid and levator scapula muscles with restricted range of motion; tenderness to palpation of rotator cuff tendons and muscles as well as at the subacromial space of bilateral shoulders and tenderness to palpation at the quadratus lumborum and lumbosacral junction with restricted range of motion. Physical exam of the right foot/ankle noted tenderness to palpation over the medial and lateral malleolus with restricted range of motion and a well-healed surgical scar. A request for authorization was submitted for Ketoprofen cream, Cyclobenzaprine cream, Synapryn, Tabradol, Deprizine, Dicopanil and fanatrex.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Synapryn 10mg/ml, 500ml:** 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 Opioids Glucosamine (and Chondroitin Sulfate) Page(s): 78-79, 50. Decision based on Non-MTUS Citation ODG: Official Disability Guidelines: Pain, Compound drugs.

**Decision rationale:** Syprasyn is a compound suspension of tramadol and glucosamine. It is considered not medically necessary. Compound medications are not considered first-line according to ODG guidelines. If other FDA-approved drugs are not effective after an adequate trial, compound drugs may be indicated. In regards to tramadol, there is no documentation all of the four As of ongoing monitoring: pain relief, side effects, physical and psychosocial functioning, and aberrant drug-related behaviors. Side effects and aberrant drug behaviors were not documented. There were no urine drug screenings or drug contract. In regards, to glucosamine, MTUS guidelines state that this may be an option for treatment of moderate arthritis especially knee osteoarthritis given its low risk. It is not indicated for the patient's medical conditions. It is unclear why the patient requires this compounded medication in lieu of taking the components separately. Therefore, the request is considered 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:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41-42. Decision based on Non-MTUS Citation ODG: Official Disability Guidelines: Pain, Compound drugs. Pain, MSM.

**Decision rationale:** Tabradol is a compound suspension of cyclobenzaprine and MSM. It is not considered medically necessary. Compound medications are not considered first-line according to ODG guidelines. If other FDA-approved drugs are not effective after an adequate trial, compound drugs may be indicated. The use of cyclobenzaprine is medically unnecessary at this point. It is indicated for short-term use with best efficacy in the first four days. The effect is modest and comes with many adverse side effects including dizziness and drowsiness. The use of cyclobenzaprine with other agents is not recommended. This muscle relaxant is useful for acute exacerbations of chronic lower back pain but not for chronic use. Therefore, continued use is considered not medically necessary. According to ODG, MSM is used for CRPS, but long-term controlled studies have not been conducted. It has not been approved for osteoarthritis. It is unclear why a compound suspension was required and why the patient could not use the components separately in tablet form. Therefore, the request is considered 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:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68. Decision based on Non-MTUS Citation ODG: Official Disability Guidelines: Pain, Compound drugs.

**Decision rationale:** Deprizine is a compound solution of ranitidine and other proprietary ingredients. Compound medications are not considered first-line according to ODG guidelines. If other FDA-approved drugs are not effective after an adequate trial, compound drugs may be indicated. The need for GI prophylaxis is not documented. According to MTUS, the patient is at low risk of GI events. He is younger than age 65, does not have a history of PUD, GI bleed or perforation, he does not use aspirin, corticosteroids, or anticoagulants, is not on high dosages or multiple NSAIDs. There were no GI complaints. Therefore, Ranitidine is considered not medically necessary. It is unclear why the patient required a compounded medication and could not take the components separately. Therefore, the request for Deprizine is considered not medically necessary.

**Dicopanол 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: Pain, Compound drugs. Mental/Stress, Diphenhydramine.

**Decision rationale:** Dicopanол is a compound suspension of diphenhydramine and other proprietary ingredients. Compound medications are not considered first-line according to ODG guidelines. If other FDA-approved drugs are not effective after an adequate trial, compound drugs may be indicated. According to ODG guidelines, Diphenhydramine is not recommended for long-term insomnia treatment which the patient is not documented to have anyways. It is unclear why the patient requires the compound form of this drug instead of the over-the counter formulation. Therefore, the request is considered 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:** Decision based on MTUS Chronic Pain Treatment Guidelines Anticonvulsants, Gabapentin Page(s): 16-19, 49. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain, Compound drugs.

**Decision rationale:** Fanatrex is a compound formulation of gabapentin and other proprietary ingredients. Compound medications are not considered first-line according to ODG guidelines. If other FDA-approved drugs are not effective after an adequate trial, compound drugs may be indicated. It is unclear why the patient requires the compound form of this drug instead of the regular tablet formulation. Therefore, the request is considered not medically necessary.