

<b>Case Number:</b>	CM14-0101000		
<b>Date Assigned:</b>	09/16/2014	<b>Date of Injury:</b>	08/13/2013
<b>Decision Date:</b>	10/07/2014	<b>UR Denial Date:</b>	05/30/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/30/2014

### 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 Occupational Medicine and is licensed to practice in California. 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:

There were 430 pages provided for this review. Per the records provided, there was a Doctor's First Report of Occupational Injury or Illness. A laundry bin fell on the claimant. The claimant tripped and fell onto the left shoulder and then went down on the knees. She hit her left shoulder on the edge of a table and then landed on both knees and complains of pain. There was reportedly a left femoral neck fracture that was closed, and a bilateral knee contusion. She was sent to orthopedics. The date of this record was August 13, 2013. There was a March 21, 2014 request for authorization. The claimant was described as a 53-year-old right-hand dominant female injured on August 13, 2013 while working as a psychiatric technician. She had injury to her left shoulder and both knees. As mentioned earlier, this record attests she was emptying out a "dirty" patient's room and the door locked on her. She attempted to get out and she tripped over a cable and fell down, landing on her left shoulder. She had x-rays. The assessment was a left shoulder strain- sprain, bilateral knee sprain-strain, rule out internal derangement of both knees, and hypertension. The patient uses several medicines including Imitrex, Lisinopril, Cyclobenzaprine, and Ketoprofen cream. They are also seeking a transcutaneous electrical nerve stimulation (TENS) unit and shockwave therapy as well as various diagnostic studies.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Compounded Ketoprofen 20% in PLO gel 120 grams QTY: 1.00: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

**Decision rationale:** The MTUS notes topical analgesic compounds are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Experimental treatments should not be used for claimant medical care. MTUS notes they are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed, but in this case, it is not clear what primary medicines had been tried and failed. Also, there is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended, is not certifiable. This compounded medicine contains several medicines untested in the peer review literature for effectiveness of use topically. Moreover, the MTUS notes that the use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. The provider did not describe each of the agents, and how they would be useful in this claimant's case for specific goals. The request is not medically necessary and appropriate.

**Compounded Cyclophene 5% in PLO gel 120 grams QTY: 1.00: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

**Decision rationale:** As shared before, this again is a compounded agent. The MTUS notes topical analgesic compounds are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Experimental treatments should not be used for claimant medical care. MTUS notes they are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed, but in this case, it is not clear what primary medicines had been tried and failed. Also, there is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended, is not certifiable. This compounded medicine contains several medicines untested in the peer review literature for effectiveness of use topically. Moreover, the MTUS notes that the use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. The provider did not describe each of the agents, and how they would be useful in this claimant's case for specific goals. The request is not medically necessary and appropriate.

**Synapryn 10mg/ml oral suspension 500ml QTY: 1.00: 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) Pain (updated 04/16/2014) Medical Food

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 12,13, 83, 113.

**Decision rationale:** Synapryn is Tramadol Hydrochloride 10 mg/mL, in oral suspension with Glucosamine in a compounded formulation). The most pharmacologically active component is the Tramadol per the MTUS; Tramadol is an opiate analogue medication, not recommended as a first-line therapy. The MTUS based on Cochrane studies found very small pain improvements, and adverse events caused participants to discontinue the medicine. Most important, there are no long term studies to allow it to be recommended for use past six months. Long term use is therefore not supported.

**Tabradol 1mg/ml oral suspension 250ml QTY: 1.00:** 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) Pain (updated 04/16/2014) Medical Food

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 41-42.

**Decision rationale:** Tabradol is a formulation of Cyclobenzaprine. The MTUS recommends Cyclobenzaprine only for a short course of therapy. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. Treatment should be brief. The addition of cyclobenzaprine to other agents is not recommended. In this case, there has been no objective functional improvement noted in the long-term use of Flexeril in this claimant. Long term use is not supported. Also, it is being used with other agents, which also is not clinically supported in the MTUS.

**Deprizine 15mg/250ml oral suspension 250ml QTY: 1.00:** 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) Pain (updated 04/16/2014) Medical Food

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, under Antidepressants

**Decision rationale:** Deprazine is an antidepressant. The MTUS is silent on this medicine. Regarding antidepressants to treat a major depressive disorder, the ODG notes: Recommended for initial treatment of presentations of Major Depressive Disorder (MDD) that is moderate, severe, or psychotic, unless electroconvulsive therapy is part of the treatment plan. Not

recommended for mild symptoms. In this case, it is not clear what objective benefit has been achieved out of the antidepressant usage, how the activities of daily living have improved, and what other benefits have been. It is not clear if this claimant has a major depressive disorder or if the medicine is for chronic pain issues. The request is not medically necessary and appropriate.

**Dicopanol 5mg/ml oral suspension 150ml QTY: 1.00: 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) Pain (updated 04/16/2014) Medical food

**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: Physician Desk References, 2014 web edition.

**Decision rationale:** Dicopanol is an oral suspension including diphenhydramine, which is an antihistamine. Per the Physician Desk Reference, this is a medicine used for allergy. The records do not portray the patient as having an allergic condition. The use of the medicine to aid the injury care is not clinically clear based on the records. Further, it is available over the counter, so the need for this special formulation is not substantiated. The request is appropriately not clinically certified.

**Fanatrex 25mg/ml oral suspension 420ml QTY: 1.00: 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) Pain (updated 04/16/2014) Medical Food

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 16,19.

**Decision rationale:** Fanatrex is an oral suspension of Gabapentin. The MTUS notes that anti-epilepsy drugs (AEDs) like Gabapentin are also referred to as anti-convulsants, and are recommended for neuropathic pain (pain due to nerve damage). However, there is a lack of expert consensus on the treatment of neuropathic pain in general due to heterogeneous etiologies, symptoms, physical signs and mechanisms. It is not clear in this case what the neuropathic pain generator is, and why therefore that Gabapentin is essential. Gabapentin (Neurontin, GabaDone, generic available) has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. This claimant however has neither of those conditions. The request is appropriately is not medically necessary and appropriate under the MTUS evidence-based criteria.