

<b>Case Number:</b>	CM15-0187660		
<b>Date Assigned:</b>	10/01/2015	<b>Date of Injury:</b>	01/25/2014
<b>Decision Date:</b>	12/04/2015	<b>UR Denial Date:</b>	09/01/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/23/2015

### 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 55-year-old male who sustained an industrial injury 1-25-2014. Diagnoses have included right knee sprain and medial meniscal tear, shin splints, right ankle sprain, right foot and toe pain and right great toe sprain. Most recent MRI of the right knee and foot and was taken 6-28-2015. Documented treatment includes physical therapy, acupuncture, chiropractic, bracing, TENS unit, extracorporeal shockwave therapy 8-31-2015, and medication including Diconopanol for sleep, and Deprizine, Dicopanol and Fanatrex which have been prescribed for at least the past six months. He was taking Gabapentin and Flurbiprofen, but is now using Synapryn and Tabradol suspension. The physician stated 8-31-2015 that this current medication regimen provides temporary relief and helps with sleep. Urine drug screening is reported to have been "consistent." The injured worker continues to present with right knee and leg pain 5-6 out of 10 described as constant, sharp, burning, and moderate to severe including numbness radiating to the foot. In 2-2015, he was reporting 7 out of 10 right knee pain. Pain continues to be aggravated with movement. He has been consistently reporting right ankle pain 3-4 out of 10, with sharp and stabbing pain in the great toe. The orthopedic surgeon's plan of care includes retro requests for Ketoprofen cream, Cyclobenzaprine cream, Synapryn, Tabradol oral suspension, Deprizine oral suspension, Dicopanol, Fanatrex oral solution, and TENS unit with supplies. All were non-certified 9-1-2015. The injured worker continues to remain off work.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retro TENS unit and supplies (unspecified DOS): 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): Transcutaneous electrotherapy.

**Decision rationale:** The above reference CA MTUS chronic pain guidelines states, TENS unit is "Not recommended as a primary treatment modality, but a one-month home-based TENS trial may be considered as a noninvasive conservative option, if used as an adjunct to a program of evidence-based functional restoration, for the conditions described below. While TENS may reflect the long-standing accepted standard of care within many medical communities, the results of studies are inconclusive; the published trials do not provide information on the stimulation parameters which are most likely to provide optimum pain relief, nor do they answer questions about long-term effectiveness. (Carroll-Cochrane, 2001)" The above referenced guidelines provides the following criteria for TENS use: "Chronic intractable pain; Documentation of pain of at least three months duration; There is evidence that other appropriate pain modalities have been tried (including medication) and failed; A one-month trial period of the TENS unit should be documented (as an adjunct to ongoing treatment modalities within a functional restoration approach) with documentation of how often the unit was used, as well as outcomes in terms of pain relief and function; rental would be preferred over purchase during this trial; Other ongoing pain treatment should also be documented during the trial period including medication usage; and A treatment plan including the specific short- and long-term goals of treatment. With the TENS unit should be submitted; A 2-lead unit is generally recommended; if a 4-lead unit is recommended, there must be documentation of why this is necessary." The documentation does not support that the IW has had a 1 month trial with improvement of symptoms of TENS unit. The IW continues with same dosing of analgesia. The request does provide details of a program for functional improvement. Without the support of the documentation, the retrospective request for a TENS unit with supplies are determined not medically necessary.

**Retro Ketoprofen 20% cream 165gm (unspecified DOS): 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, the request does not include the frequency or location of applications. As this medication is not supported by the guidelines or FDA approved, the request is determined not medically necessary.

**Retro Cyclobenzaprine 5% cream 100gm (unspecified DOS): 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 chronic pain guidelines, topical analgesics are "largely experimental in use with few randomized controlled trials to determine efficacy or safety." Guidelines also state "Many agents are compounded as monotherapy or in combination for pain control... There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug that is not recommended is not recommended." The requested medication is cyclobenzaprine. CA MTUS guidelines states that "There is no evidence for use of any other muscle relaxant as a topical product." Additionally, the request does not include dosing frequency, location of application, or duration of use. With the support of the guidelines, the request is determined not medically necessary.

**Retro Synapryn 10mg/1ml 500ml (unspecified DOS): 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): Opioids, criteria for use, Opioids for chronic pain, Opioids, specific drug list. 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. Additionally, the request does not include dosing or frequency. The combination preparation is not supported and therefore, not medically necessary.

**Retro Tabradol 1mg/1ml oral suspension 250ml (unspecified DOS): 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 CaMTUS 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. The request does not include dosing or frequency. Per the MTUS, cyclobenzaprine is not indicated and is not medically necessary.

**Retro Deprizine 15mg/ml oral suspension 250ml (unspecified DOS): 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 protectant 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. Additionally, the request does not include frequency or dosing. Deprizine is not medically necessary based on the MTUS.

**Retro Dicopanor 5mg/ml oral suspension 150ml (unspecified DOS): 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) Treatment Index 13th Edition (web) 2015 Pain, Insomnia treatment.

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

**Decision rationale:** According to the above reference, Dicopanor is a combination of antihistamine and other proprietary ingredients. Unknown components of a medication cannot

be evaluated to determine their safety or medical necessity. Furthermore, the reference states "This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA." The request does not include dosing or frequency. As such, the request for Dicopanol is determined not medically necessary.

**Retro Fanatrex 25mg/ml oral suspension 420ml (unspecified DOS): 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. Additionally, the request does not include dosing or frequency. As such, the request for Fanatrex is not medically necessary.