

<b>Case Number:</b>	CM14-0198078		
<b>Date Assigned:</b>	12/08/2014	<b>Date of Injury:</b>	07/21/2014
<b>Decision Date:</b>	01/22/2015	<b>UR Denial Date:</b>	10/30/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/25/2014

### 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 Emergency 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:

Patient with reported date of injury on 7/21/2014. Mechanism of injury is described as "excessive typing and handling of phone calls". Patient has a diagnosis of cervicalgia, extremity pain and arthralgia of the shoulder. Orthopedist documents diagnosis of "clinical evidence of C5-6 disc herniation" and R shoulder impingement. Medical reports reviewed. Last report available until 10/15/14. Patient complains of neck pain radiating to shoulder. Also has some weakness and numbness to shoulder. Objective exam reveals normal posture and gait. Tenderness to trapezius muscles with marked spasms. Range of motion is limited. Neurogenic compression testing is positive. R shoulder exam has tenderness to palpation to anterior shoulder. No spasms. Full range of motion. Strength is normal except for mild weakness to supraspinatus. Impingement test is positive. Multiple medications requested was started by the orthopedists. No justification or rationale for decision was documented. There are no provided advance imaging or electrodiagnostic reports. Patient is undergoing physical therapy. Has had prior therapy in the past. Medications noted to be Robin and Tramadol. Patient received trigger point injection on 9/17/14. Independent Medical Review is for Orphenadrine/Caffeine 50/10mg #60, Gabapentin/Pyridoxine 250mg/10mg #60, Omeprazole/Flurbiprofen 10/100mg #60, Flurbiprofen/Cyclobenzaprine/Menthol 20/10/40% #180g and Keratek gel #4oz. Prior UR on 10/29/14 recommended non-certification.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**1 Prescription for Orphenadrine/caffeine 50/10mg, #60: 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 Muscle Relaxants(for pain) Page(s): 63-65. Decision based on Non-MTUS Citation <http://www.accessdata.fda.gov/>

**Decision rationale:** Orphenadrine is a muscle relaxant. Review of FDA drug database does not show an approved Orphenadrine and caffeine combination medication. There is only an approved combination of Orphenadrine, Aspirin and Caffeine. This provider has ordered multiple compounded products therefore since there is no FDA approved combination; it is assumed that this request is for a compounded product. As per MTUS Chronic pain guidelines concerning muscle relaxants show that orphenadrine is only recommended for short term use and has limited data to show efficacy. It has significant anticholinergic side effects and may lead to euphoria and other side effects. Caffeine is believed to cause a potentiating effect in combination with orphenadrine. There is no documentation as to why this provider has requested a compounded product. Pt was previously on another muscle relaxant with no documentation of benefit. The number of tablets also do not support short term use. The request for a non-FDA approved compounded product with significant side effects, excessive number of tablets prescribed does not meet any indication for recommendation. Orphenadrine/Caffeine is not medically necessary.

**. 1 Prescription for Gabapentin/Pyridoxine 250/10mg, #60: 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 Antiepilepsy drugs(AEDs) Page(s): 18-19.

**Decision rationale:** Gabapentin(Neurontin) is an anti-epileptic drug with efficacy in neuropathic pain. It is most effective in polyneuropathic pain. Pyridoxine is Vitamin B6. There is some belief that it may aid in neuropathic pain but evidence and studies have found that belief to be false. Review of FDA drug database does not show an approved Gabapentin and pyridoxine combination medication. This is an obvious compounded product. There is no documentation as to why this provider has requested a compounded product. While gabapentin may have some benefit, this provider has ordered a non-FDA approved compounded substance with no rationale or justification. Gabapentin/Pyridoxine is not medically necessary.

**1 Prescription for Omeprazole/Flurbiprofen 10/100mg, #60: 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 and cardiovascular risk Page(s): 68-69.

**Decision rationale:** Review of FDA drug database does not show an approved Flurbiprofen and Omeprazole combination medication. This is an obvious compounded product. There is no documentation as to why this provider has requested a compounded product. Flurbiprofen is an NSAID. It may have some short term benefit in pain control. Omeprazole/Prilosec is a proton-pump inhibitor(PPI) which is used to treat gastritis/peptic ulcer disease, acid reflux or dyspepsia from NSAIDs. The requested flurbiprofen to be compounded into this medication is not medically necessary. There is no documentation of dyspepsia or increased risk of GI bleed. Since patient has no indication for PPI and NSAID is not recommended, Omeprazole is not medically necessary. This is an inappropriately compounded product with no rationale justification for approval. Flurbiprofen may have some benefit but is has been inappropriately requested to be compounded with omeprazole. Flurbiprofen/Omeprazole is not medically necessary.

**1 Prescription for Flurbiprofen/Cyclo/Menthol 20/10/4% cream, 180 mg:** 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): 111-113.

**Decision rationale:** As per MTUS guidelines "Any compound product that contains a drug or drug class that is no recommended is not recommended."1) Flurbiprofen: Topical NSAIDs are shown to be superior to placebo. It should not be used long term. It may be useful. Flurbiprofen is not FDA approved for topical application. There is no justification by the provider as to why the patient requires a non-FDA approved compounded NSAID when there are multiple other approved products including over the counter medications on the market. Flurbiprofen is not medically necessary. 2) Cyclobenzaprine is an oral muscle relaxant. It is not FDA approved for topical application. MTUS guidelines do not recommend topical use. It is not medically recommended or appropriate.3) Menthol: There is no information in the MTUS Chronic pain, ACOEM guidelines of Official Disability Guidelines concerning menthol. There appears to be some topical soothing effect but no evidence is available to support this affect.Since Flurbiprofen and Cyclobenzaprine is not medically necessary, this compounded product is not medically necessary.

**1 Prescription for Keratek Gel, #4 Oz:** 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): 111-113.

**Decision rationale:** The requested product is a patch composed of multiple medications. As per MTUS guidelines, "Any compounded product that contain one drug or drug class that is not recommended is not recommended." Kera-Tek is a brand specific medication containing methyl-salicylate and menthol. 1) Methyl-Salicylate: As per MTUS Chronic pain guidelines, methyl-Salicylate is recommended for osteoarthritis especially of the knee. It may be recommended for certain chronic musculoskeletal pains for short term treatment. There is no evidence for its efficacy in the spine, hip or shoulder. Patient has spine and shoulder pains. It is not medically necessary. 2) Menthol: There is no information in the MTUS Chronic pain, ACOEM guidelines of Official Disability Guidelines concerning menthol. There appears to be some topical soothing effect but no evidence is available to support this affect. The request is specific to a brand name product. There is no documentation as to why Kera-Tek was specially requested. Methyl-salicylate is not recommended therefore Kera-Tek is not medically necessary.