

<b>Case Number:</b>	CM14-0023665		
<b>Date Assigned:</b>	06/11/2014	<b>Date of Injury:</b>	06/07/2013
<b>Decision Date:</b>	07/21/2014	<b>UR Denial Date:</b>	01/21/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/25/2014

### 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 Physical Medicine and Rehabilitation, has a subspecialty in Neuromuscular Medicine and is licensed to practice in Maryland. 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:

The patient is a 36 year old female with a work injury dated June 7, 2013, and diagnosis of adhesive capsulitis. An MRI of the cervical spine dated November 12, 2013 revealed the following findings: (1) C5-6: There is mild loss of disk signal with a 4 to 5-mm left paracentral focal extrusion with partial osteophytic ridging, which moderately flattens the left anterior cord and narrows the left lateral canal. Left uncinat hypertrophy moderately narrows the left neural foramen; (2) C6-7: There is mild loss of disc signal with a 2-mm right paracentral protrusion, which mildly flattens the anterior thecal sac effacing, but does not compress the cord. And the neural foramina are patent. An MRI of the shoulder dated November 15, 2013 revealed no significant cuff tears, AC joint hypertrophic changes with a curved acromion abutting the cuff and scant adjacent, subacromial subdeltoid bursal fluid, prominent capsular thickness along the axillary pouch as well as along the subscapular recess. The documentation submitted reveals that the patient had an office visit on December 4, 2013. She reported severe pain with loss of motion in the right shoulder. Range of motion was limited in flexion, extension, and abduction with no internal or external rotation. Her shoulder MRI was consistent with adhesive capsulitis. The patient has undergone prior treatment including physical therapy, two injections, medications, rest; and remains disabled. Authorization was requested for a manipulation under anesthesia (MUA) and capsular release. She was dispensed Hydrocodone 10/325mg #60, Diclofenac Sodium, Pantoprazole Sodium 20mg #60 and Cyclobenzaprine 7.5 mg #90. The progress report for a follow up shoulder examination dated January 8, 2014 states that the patient continues to have on and off throbbing pain with numbness in the right hand. She reports that the right shoulder surgery was denied, and that on a scale from 1 to 10 with 10 being the worst, her pain level is an 8. She complains of not being able to lay down on the shoulder, and that she is unable

to use it for long periods of time due to pain and numbness. X-rays of the right shoulder and right humerus show persistent acromial spurring. The treatment plan included proceeding with arthroscopy of the right shoulder with MUA and capsular release. The patient received an intra-articular cortisone injection under sterile conditions with ultrasound guidance to the right shoulder to help give pain relief. She was also given a prescription for Dyotin SR, Flurbitac, Theraflex Cream, and Vicosetron.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **DYOTIN SR 250MG #60 PRESCRIBED ON 01-08-14,:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS, COMPOUNDED.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** Dyotin SR 250mg #60 prescribed on January 8, 2014 is not medically necessary per the MTUS Chronic Pain Medical Treatment Guidelines. Dyotin is a compounded medication which contains Gabapentin 250mg and Pyridoxine. The documentation does not indicate the medical necessity of Pyridoxine which is a vitamin. The documentation does not indicate the patient complains of neuropathic pain. Furthermore, the MTUS Guidelines do not support the use of topical Gabapentin, as there is no peer-reviewed literature to support the use. Based on her imaging and clinical exams her diagnosis is consistent with adhesive capsulitis. The medical necessity of Dyotin is not established and therefore Dyotin SR 250mg #60 prescribed on January 8, 2014 is not medically necessary.

#### **FLURBITAC 100/100MG #60 PRESCRIBED ON 01-08-14,:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS, COMPOUNDED.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics, NSAIDs, GI Symptoms & Cardiovascular Risk Page(s): 111-113 and 69.

**Decision rationale:** Flurbitac 100/100mg #60 prescribed on January 8, 2014 is a compound medication consisting of Flurbiprofen 100mg and Ranitidine 100mg. The patient has adhesive capsulitis, but imaging reveals hypertrophic changes on shoulder, which suggests osteoarthritis. The MTUS guidelines state that there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the shoulder. The patient does not have any risk factors requiring a proton pump inhibitor on the documentation submitted. The guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended for use overall. Therefore, the request for Flurbitac 100/100mg #60 prescribed on January 8, 2014 is not medically necessary.

**THERAFLEX CREAM 180MG PRESCRIBED ON 01-08-14: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS, COMPOUNDED.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Salicylate topicals Page(s): 111-113 and 105.

**Decision rationale:** Theraflex cream 180mg prescribed on January 8, 2014 is not medically necessary per the MTUS Chronic Pain Medical Treatment Guidelines. The guidelines state that there is little use to support the use of many of these agents. Additionally, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended for use. Theraflex cream contains Cyclobenzaprine which is a muscle relaxant. The guidelines do not support the use of Cyclobenzaprine as a topical analgesic or muscle relaxant. Additionally, Theraflex Cream contains Flurbiprofen. The MTUS guidelines state that the efficacy in clinical trials for this treatment (topical NSAIDS) has been inconsistent. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. Menthol is an ingredient in Ben Gay which is supported by the MTUS guidelines. Due to the fact that topical Cyclobenzaprine is not recommended, the entire compound of Theraflex is not medically necessary. Therefore Theraflex cream 180mg prescribed on January 8, 2014 is not medically necessary.

**VICOSETRON 10/300/2MG #40 PRESCRIBED ON 01/08/2014: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS, COMPOUNDED.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

**Decision rationale:** Vicosetron 10/300/2mg #40 prescribed on January 8, 2014 is not medically necessary per the MTUS Chronic Pain Medical Treatment Guidelines. Vicosetron contains Hydrocodone, and the documentation is not clear what other medication this compounded medication contains. The guidelines state the topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended for use. The guidelines do not support the use of topical opioids due to little research to support these agents. The documentation is not clear on why the patient cannot take oral medication. The request for Vicosetron 10/300/2mg #40 prescribed on January 8, 2014 is not medically necessary.

**KERATEK GEL 4OZ BOTTLE PRESCRIBED ON 01/08/2014: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Compounded.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate topicals, Topical analgesics Page(s): 105 and 111-113.

**Decision rationale:** Keratek gel 4 oz bottle prescribed on January 8, 2014 is not medically necessary per the MTUS Chronic Pain Medical Treatment Guidelines. Keratek is a compounded gel that contains methyl salicylate and menthol. These are the same ingredients contained in ultra strength Ben Gay. The documentation is not clear on why the patient cannot take over the counter Ben Gay rather than this prescription strength. There is no documentation that he has failed Ben Gay. The request for Keratek gel 4 oz bottle prescribed on January 8, 2014 is not medically necessary.