

<b>Case Number:</b>	CM15-0110412		
<b>Date Assigned:</b>	06/17/2015	<b>Date of Injury:</b>	04/06/2012
<b>Decision Date:</b>	09/18/2015	<b>UR Denial Date:</b>	05/12/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/08/2015

### 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: California

Certification(s)/Specialty: Preventive Medicine, Occupational 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 female who sustained an industrial injury on 4/6/12. The diagnoses have included cervical spine multilevel herniated nucleus pulposus (HNP); cervical spine multilevel degenerative disc disease; cervical spine radiculopathy; bilateral shoulder impingement syndrome, rotator cuff tear and tenosynovitis and left elbow sprain and strain. Treatment to date has included physiotherapy and medications. On recent exam the injured worker had continued complaints of burning, radicular neck pain and muscle spasms, bilateral shoulder pain radiating down the arms to the fingers associated with muscle spasm and burning bilateral elbow pain and muscle spasms; burning bilateral wrist pain and muscle spasms; burning radicular mid back pain and muscle spasms; burning, radicular low back pain and muscle spasms and bilateral knee pain and muscle spasms. Medication lowers pain and improves function and she has no side effects from the medication. Cervical spine examination revealed tenderness to palpation at occiputs, the trapezius, the levator scapula, the splenius and the scalene and at the sternocleidomastoid muscles. Bilateral shoulder examination revealed there is tenderness to palpation at the trapezius, supraspinatus, the levator scapula and the rhomboid muscles and palpable tenderness noted at the subacromial space. Bilateral elbow examination revealed that there is mild tenderness to palpation at the epicondyles and bilateral wrist has tenderness to palpation at the triangular fibrocartilage complex, at the extensor carpal ulnaris, the first dorsal muscle compartment and at the carpal tunnel. The request was for tabradol 1mg/ml oral suspension 250ml (5ml 2-3 times per day), #1; synapryn 10mg/1ml oral suspension 500ml (5ml

3 times a day), #1; cyclobenzaprine 5% cream 100gm (apply thin layer 3 times a day), #1 and ketoprofen 20% cream 165gm (apply thin layer to affected area 3 times a day), #1.

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

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

#### **Tabradol 1mg/ml oral suspension 250ml (5ml 2-3 times per day), #1: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain), Antispasmodics Page(s): 63, 64.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines Cyclobenzaprine; Muscle relaxants (for pain) Page(s): 41-2, 63-66.

**Decision rationale:** Tobradol is a compounded medication containing cyclobenzaprine and methylsulfonylmethane (MSM). Cyclobenzaprine is classified as a sedating skeletal muscle relaxant. This class of medications can be helpful in reducing pain and muscle tension thus increasing patient mobility. Muscle relaxants as a group, however, are recommended for short-term use only as their efficacy appears to diminish over time. In fact, studies have shown cyclobenzaprine's greatest effect is in the first 4 days of treatment after which use may actually hinder return to functional activities. They are considered no more effective at pain control than non-steroidal anti-inflammatory medication (NSAIDs) and there is no study that shows combination therapy of NSAIDs with muscle relaxants have a demonstrable benefit. MSM is a dietary supplement which some researchers have suggested has anti-inflammatory effects and there are some small scale trials that suggest benefit from MSM in patients with osteoarthritis. It is marketed to support the structure and function of joints, however, there is little scientific evidence to support this use. It is important to note that in America it is illegal to market any dietary supplement as a treatment for any disease or condition. This patient has been on Tobradol therapy for over one month. There is no documented provider instruction to use this medication on an intermittent or "as needed" basis. Since chronic use of muscle relaxant therapy is not recommended by the MTUS, continued use of this medication is not indicated. Medical necessity for use of this medication has not been established. Therefore, the request is not medically necessary.

#### **Synapryn 10mg/1ml oral suspension 500ml (5ml 3 times a day), #1: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate); Opioids, specific drug list Page(s): 50, 93-94.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-9, Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate); Medications for chronic pain; Opioids Page(s): 50, 60-1, 74-96.

**Decision rationale:** Synapryn is a combination product composed of tramadol and glucosamine. Tramadol is a narcotic pain reliever with mu-receptor opioid agonist activity and is used to treat moderate to severe pain. Tramadol ER is an extended release formulation of this medication. Appropriate dosing should not exceed 400 mg/day and it should be used with caution in any patient taking Selective Serotonin Reuptake Inhibitors (SSRI) as together they

may cause a potentially fatal condition known as Serotonin Syndrome. There are no studies showing effective use of this medication for chronic pain that lasts greater than 3 months. However, the MTUS describes use of narcotics for control of chronic pain. Even though this is not considered a first-line therapy, the chronic use of narcotics is a viable alternative when other therapeutic modalities have been tried and failed. Success of this therapy is noted when there is significant improvement in pain or function. The risk with this therapy is the development of addiction, overdose or death. The pain guidelines in the MTUS directly address this issue and have criteria for the safe use of chronic opioids. Glucosamine is a medical nutritional supplement. It is marketed to support the structure and function of joints, however, there is little scientific evidence to support this use. It is important to note that in America it is illegal to market any dietary supplement as a treatment for any disease or condition. The MTUS only recommends its use in low risk patients with moderate arthritis. This patient has diagnoses appropriate for use of both of these compounds, the provider is appropriately monitoring the patient for safe use of chronic opioid therapy and the medication is effective in lessening the patient's pain. Medical necessity for the continued use of this medication has been established. Therefore, the request is medically necessary.

**Cyclobenzaprine 5% cream 100gm (apply thin layer 3 times a day), #1: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Muscle relaxants (for pain) Page(s): 41-2, 63-6, 111-13.

**Decision rationale:** Cyclobenzaprine is classified as a sedating skeletal muscle relaxant. Cyclobenzaprine Cream is this medication formulated for topical use. This class of medications can be helpful in reducing pain and muscle tension thus increasing patient mobility. Muscle relaxants as a group, however, are recommended for short-term use only as their efficacy appears to diminish over time. In fact, studies have shown cyclobenzaprine's greatest effect is in the first 4 days of treatment after which use may actually hinder return to functional activities. The use of topical agents to control pain is considered an option although it is considered largely experimental, as there is little to no research to support their use. The MTUS does not address the topical use of cyclobenzaprine specifically but notes that there is no evidence of effectiveness of any muscle relaxant as a topical product. Since there is no acceptable scientific literature to support its use medical necessity for this medication has not been established. Therefore, the request is not medically necessary.

**Ketoprofen 20% cream 165gm (apply thin layer to affected area 3 times a day), #1: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs); Topical Analgesics Page(s): 67-73, 111-13. Decision based on Non-MTUS Citation FDA list of Approved Medications available at: <http://www.accessdata.fda.gov/scripts/cder/ob/docs/tempai.cfm>.

**Decision rationale:** Ketoprofen cream is a non-steroidal anti-inflammatory (NSAIDs) medication formulated for topical use. The systemic form of this medication is indicated for

treatment of mild to moderate pain. Topical NSAIDs have been effective in short-term use trials for chronic musculoskeletal pain but long-term use has not been adequately studied. In general, the use of topical agents to control pain is considered an option by the MTUS although it is considered largely experimental, as there is little to no research to support their use. Although most topical analgesics are recommended for treatment of neuropathic pain, topical NSAIDs are primarily recommended for treatment of osteoarthritis and tendonitis in joints amenable to its use, such as the knee or elbow. There is little evidence to support its use in treating inflammatory conditions of the hip or spine such as diagnosed for this patient. The MTUS notes that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." MTUS does not recommend use of topical ketoprofen because it is not FDA approved for this use. Medical necessity for use of this formulation of ketoprofen has not been established. Therefore, the request is not medically necessary.