

<b>Case Number:</b>	CM15-0029455		
<b>Date Assigned:</b>	02/23/2015	<b>Date of Injury:</b>	01/14/2013
<b>Decision Date:</b>	04/14/2015	<b>UR Denial Date:</b>	01/27/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/17/2015

### 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, Arizona  
 Certification(s)/Specialty: Physical Medicine & Rehabilitation

### 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 50-year-old male who reported injury on 01/14/2013. The mechanism of injury was cumulative trauma and a lifting injury. The diagnoses included right shoulder labral tear with anterior instability and impingement. The injured worker's prior treatments include medication, acupuncture, and chiropractic care. The injured worker underwent an MR arthrogram of the right shoulder on 07/16/2014. Additionally, the injured worker had utilized additional therapies. The injured worker had utilized TENS unit and topical creams which helped. The documentation of 02/26/2015 revealed the injured worker had complaints of low back pain. The injured worker had constant pain and the pain was an 8/10 to 9/10 in severity. The injured worker had more severe pain in the right lumbosacral area radiating to the right lower extremity. The injured worker had tenderness in the SI joint and PSIS bilaterally. The injured worker had tenderness to the facet joints and tenderness over the spinous process of the lumbar spine. The straight leg raise was positive on the right at 50 degrees, and caused back pain in the supine position. The faber test was positive on the right. The injured worker had decreased range of motion. The diagnoses included low back pain with radiating symptoms to the right lower extremity, right SI joint arthropathy, and rule out lumbar spondylosis. The treatment plan included Norco 10/325 mg twice a day as needed for breakthrough pain #60, tizanidine 4 mg 1 to 2 tablets at bedtime for muscle relaxation and help with insomnia secondary to pain, and compound cream to be applied to the bilateral lumbosacral area for symptomatic relief.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**(1) Jar of Tramadol 8%, Gabapentin 10%, Menthol 2%, Camphor 2%, Capsaicin 0.05%, 120 grams:** 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 Tramadol; Gabapentin; Topical Capsaicin; Topical Analgesics; Topical Salicylates Page(s): 82; 113; 28; 111; 105. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: FDA.gov.

**Decision rationale:** The California Medical Treatment Utilization Schedule indicates that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Salicylates are recommended. A thorough search of FDA.gov did not indicate there was a formulation of topical Tramadol that had been FDA approved. The approved form of Tramadol is for oral consumption, which is not recommended as a first line therapy. Gabapentin: Not recommended. There is no peer-reviewed literature to support use Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. The guidelines recommend Topical Salicylates. The clinical documentation submitted for review indicated the injured worker had utilized topical creams. However, the efficacy was not provided. There was a lack of documentation of exceptional factors to warrant nonadherence to guideline recommendations. The request as submitted failed to indicate the body part and frequency to be treated. Given the above, the request for (1) Jar of Tramadol 8%, Gabapentin 10%, Menthol 2%, Camphor 2%, Capsaicin 0.05%, 120 grams is not medically necessary.

**Tizanidine 4mg Qty 60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antispasticity/Antispasmodic drugs, Muscle relaxants Page(s): 63.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63.

**Decision rationale:** The California Medical Treatment Utilization Schedule guidelines recommend muscle relaxants as a second line option for the short-term treatment of acute low back pain and their use is recommended for less than 3 weeks. There should be documentation of objective functional improvement. The clinical documentation submitted for review indicated the injured worker had utilized the medication for an extended duration of time. There was a

lack of documentation of objective functional benefit and there was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Tizanidine 4mg Qty 60 is not medically necessary.

**Norco 10 mg/325 mg Qty 60 with (3) refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic pain; ongoing management; opioid dosing Page(s): 60; 78; 86. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://www.dea.gov/index.shtml>.

**Decision rationale:** The California Medical Treatment Utilization Schedule guidelines recommend opiates for chronic pain. There should be documentation of an objective improvement in function, an objective decrease in pain, and evidence that the injured worker is being monitored for aberrant drug behavior and side effects. On October 6, 2014, the Drug Enforcement Administration (DEA) decision to restrict access to hydrocodone combination pain relievers (HCPs) went into effect. Medications like Lortab, Norco, Vicodin and generic formulations have been moved from Schedule III to Schedule II. The clinical documentation submitted for review failed to provide documentation of objective functional improvement, an objective decrease in pain, and documentation the injured worker is being monitored for aberrant drug behavior and side effects. There was a lack of documentation of exceptional factors to warrant non-adherence to DEA guidelines. Given the above and the lack of documentation, the request for Norco 10 mg/325 mg Qty 60 with (3) refills is not medically necessary.