

<b>Case Number:</b>	CM15-0133130		
<b>Date Assigned:</b>	07/21/2015	<b>Date of Injury:</b>	10/01/2014
<b>Decision Date:</b>	08/21/2015	<b>UR Denial Date:</b>	06/08/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/09/2015

### 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

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 63 year old female, who sustained an industrial injury on October 1, 2014. She reported trying to catch one of her patients as she fell with pain in the neck and upper arm. The injured worker was diagnosed as having hand sprain/strain, wrist sprain/strain, and carpal tunnel, repetitive motion syndrome, De Quervain's tenosynovitis, tendinitis, lumbar spine sprain/strain, thoracic spine sprain/strain, muscle spasms, left shoulder impingement syndrome. Treatments and evaluations to date have included physical therapy, splinting, x-rays, left shoulder subacromial injection, MRI, and medication. Currently, the injured worker complains of painful and tight upper back, lower back, bilateral hands, wrists and left knee. The Primary Treating Physician's report dated June 1, 2015, noted the injured worker had left shoulder spasms and decreased range of motion (ROM) with lumbar spine pain at L1-S1. The Physician noted that due to the injured worker's history of stomach upset with non-steroid anti-inflammatory drugs (NSAIDs) which can cause gastritis. He was prescribing Prilosec, along with other medications including Diclofenac, LidoPro Pain Relief Ointment, and Cyclobenzaprine. The treatment plan was noted to include medication prescriptions and a request for authorization for physical therapy. The injured worker was noted to be able to return to modified work as of June 1, 2015.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Diclofenac 100 mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 46.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67, 68, 71. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain Chapter, Diclofenac.

**Decision rationale:** The MTUS Chronic Pain Medical Treatment Guidelines notes all chronic pain therapies are focused on the goal of functional restoration rather than merely the elimination of pain, and assessment of treatment efficacy is accomplished by reporting functional improvement. The guidelines indicates "Functional improvement" is evidenced by a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management...and a reduction in the dependency on continued medical treatment." The guidelines recommend non-steroid anti-inflammatory drugs (NSAIDs) for osteoarthritis recommended at the lowest dose for the shortest period in patients with moderate to severe pain. The FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect. There is no evidence of long-term effectiveness for pain or function. The Official Disability Guidelines (ODG) notes that Diclofenac is not recommended as a first line therapy due to an increased risk profile as it increases the risk of cardiovascular events by about 40%. Treatment with all oral and topical Diclofenac products may increase liver dysfunction, and use has resulted in liver failure and death, and physicians should measure transaminases periodically in patients receiving long-term therapy with Diclofenac. "With the lack of data to support superiority of Diclofenac over other NSAIDs and the possible increased hepatic and cardiovascular risk associated with its use, alternative analgesics and/or nonpharmacological therapy should be considered." The injured worker was noted to have prescribed Diclofenac since at least December 2014, without documentation of a failed first line NSAID, or with an indication as to why the medication was prescribed or that the physician had discussed the cardiovascular risks with the injured worker. The documentation provided did not include any laboratory evaluations, or indication from the physician that the injured worker's transaminases were being monitored. The documentation provided did not include documentation of objective, measurable improvement in the injured worker's pain, function, work status, ability to perform specific activities of daily living (ADLs), or dependency on medical care with use of the Diclofenac. Therefore, based on the guidelines, the documentation provided did not support the medical necessity of the request for Diclofenac 100 mg #60.

**Lidopro 121gm:** 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 Topical analgesics Page(s): 111-113.

**Decision rationale:** The MTUS Chronic Pain Medical Treatment Guidelines note topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed, and that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The guidelines note that these medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. The requested compound medication of LidoPro has the active ingredients of Capsaicin, Lidocaine, Menthol, and Methyl Salicylate. The guidelines note that Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Lidocaine is recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain and also used off-label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Lidocaine is not recommended for non-neuropathic pain. The documentation provided failed to include the injured worker's response to the Lidopro with objective, measurable improvement in pain and functionality, or any indication that the injured worker had not responded, or was intolerant to other treatments. The compounded medication also included Lidoderm, which is not recommended in that form. The treating physician's request did not include the site of application or directions for use of the requested LidoPro. As such, the prescription is not sufficient and based on the guidelines and the documentation provided, the request for Lidopro 121gm is not medically necessary.

**Cyclobenzaprine 7.5 mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain) Page(s): 41-42.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants Page(s): 63-64.

**Decision rationale:** The CA MTUS Chronic Pain Medical Treatment Guidelines notes all chronic pain therapies are focused on the goal of functional restoration rather than merely the elimination of pain, and assessment of treatment efficacy is accomplished by reporting functional improvement. The guidelines recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain as they may be effective in reducing pain and muscle tension, and increasing mobility, however, in most low back pain cases, they show no benefit beyond non-steroid anti-inflammatory drugs (NSAIDs) in pain and overall improvement. There is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. Cyclobenzaprine (Flexeril) is recommended for a short course of therapy, with limited, mixed-evidence not allowing for a recommendation for chronic use, recommended to be used no longer

than two to three weeks. The injured worker was noted to have been prescribed the Cyclobenzaprine since at least April 28, 2015, which far exceeds the recommended two to three weeks of therapy without documentation of an acute exacerbation of symptoms. The documentation provided did not include documentation of objective, measurable improvement in the injured worker's pain, function, ability to perform specific activities of daily living (ADLs), work status, or dependency on medical care with the use of the Cyclobenzaprine. Therefore, based on the guidelines, the documentation provided did not support the medical necessity of the request for Cyclobenzaprine 7.5 mg #60.

**Omeprazole 20 mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS (Non-Steroidal Anti-Inflammatory Drugs) GI (Gastrointestinal) Symptoms & Cardiovascular Risk Page(s): 68.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS GI symptoms & cardiovascular risk Page(s): 68-69.

**Decision rationale:** Per the CA MTUS Chronic Pain Medical Treatment Guidelines, co-therapy with a nonsteroidal anti-inflammatory medication (NSAID) and a proton pump inhibitor (PPI) is "not indicated in patients other than those at intermediate or high risk for gastrointestinal events (including age > 65 years, history of peptic ulcer, gastrointestinal (GI) bleeding or perforation, concurrent use of aspirin, corticosteroids and/or an anticoagulant, or high dose/multiple NSAIDS such as NSAID plus low dose aspirin). The guidelines are specific regarding the risk factors of history of peptic ulcer or GI bleeding or perforation, not just a GI history (which could include many other GI issues). The documentation provided noted the injured worker was on NSAID therapy and Omeprazole, a proton pump inhibitor (PPI) due to the injured worker's history of stomach upset with NSAIDS. The documentation does not include an abdominal examination, report of ongoing discomfort, or documentation of any gastrointestinal evaluation. Additionally, the current request for the NSAID Diclofenac has not been found to be medically necessary. The request for Omeprazole 20 mg #60 is not medically necessary.