

<b>Case Number:</b>	CM15-0202690		
<b>Date Assigned:</b>	10/21/2015	<b>Date of Injury:</b>	06/09/2009
<b>Decision Date:</b>	12/24/2015	<b>UR Denial Date:</b>	09/22/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/14/2015

### 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: 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 59 year old female, who sustained an industrial injury on 06-09-2009. A review of the medical records indicates that the injured worker (IW) is undergoing treatment for lumbar strain or sprain, probable herniated disc in the lumbar spine, and lower extremity weakness (rule out radiculopathy). Medical records (03-09-2015) indicate ongoing low back pain with radiating pain into the bilateral lower extremities. Pain levels were rated 0 out of 10 in severity on a visual analog scale (VAS), but was described as sharp, aching, dull, burning, cramping, and pin-and-needles like. Activity levels and level of functioning were not specifically discussed. Per the treating physician's progress report (PR), the IW could return to modified work duties. The physical exam, dated 03-09-2015, provided no objective findings. Relevant treatments have included: work restrictions, and pain medications. It was unclear what medications the IW was currently taking or how long they had been prescribed as there were no previous PRs available for review. The request for authorization (09-01-2015) shows that the following medications and services were requested: Norco 10-325mg #60, Motrin 800mg, Prilosec 20mg, Flexeril 100mg #15, Flurbi (NAP) cream-LA 180gm, Gabacyclotram cream 180gm, 6 sessions of physiotherapy for the low back, a left L5-S1 epidural steroid injection, and a urine drug screen. The original utilization review (09-22-2015) approved the request for Motrin 800mg #30, and non-certified the requests for Norco 10-325mg #60, Prilosec 20mg, Flexeril 100mg #15, Flurbi (NAP) cream-LA 180gm, Gabacyclotram cream 180gm, 6 sessions of physiotherapy for the low back, a left L5-S1 epidural steroid injection, and a urine drug screen.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Norco 10/325mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**Decision rationale:** The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. As part of the pain treatment agreement, it is advised that, "Refills are limited, and will only occur at appointments." In this case, there is inadequate documentation of persistent functional improvement seen. Functional improvement means either 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 visit and a reduction in the dependency on continued medical treatment. As such, the request is not indicated. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome. Therefore the request is not medically necessary.

**Motrin 800mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic)/NSAIDs (non-steroidal anti-inflammatory drugs).

**Decision rationale:** The request is for the use of a medication in the NSAID class. The ODG state the following regarding this topic: Specific recommendations: Osteoarthritis (including knee and hip), are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular, or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although 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 (with Naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function (Chen, 2008), (Laine, 2008). Back Pain - Acute low back pain & acute exacerbations of chronic pain are recommended as a second-line treatment after acetaminophen. In general, there is conflicting to negative evidence that NSAIDs are more effective than acetaminophen for acute LBP (van Tulder, 2006), (Hancock, 2007). For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects (Roelofs-Cochrane, 2008). The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician (Hancock, 2007). Back Pain - Chronic low back pain is recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another (Roelofs-Cochrane, 2008). See also Anti-inflammatory medications. Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in patients with neuropathic pain (Namaka, 2004), (Gore, 2006). See NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; & Medications for acute pain (analgesics). Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage (Maroon, 2006). The risks of NSAIDs in older patients, which include increased cardiovascular risk and gastrointestinal toxicity, may outweigh the benefits of these medications (AGS, 2009). As stated above, acetaminophen would be considered first-line treatment for chronic pain. In this case, the continued use of an NSAID is not supported. This is secondary to inadequate documentation of functional improvement benefit seen. Also, the duration of use places the patient at risk for gastrointestinal and cardiovascular side-effects. In addition, it is known that use of NSAIDs delays the healing of soft tissue including ligaments, tendons, and cartilage. As such, the request is not indicated. Therefore the request is not medically necessary.

**Prilosec 20mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** The request is for the use of a medication in the class of a proton pump inhibitor. It is indicated for patients with peptic ulcer disease. It can also be used as a preventative measure in patients taking non-steroidal anti-inflammatories for chronic pain. Unfortunately, they do have certain side effects including gastrointestinal disease. The MTUS guidelines states that patients who are classified as intermediate or high risk, should be treated prophylactically. Criteria for risk are as follows: (1) age over 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Due to the fact the patient does not meet to above stated criteria, the request for use is not indicated. Therefore the request is not medically necessary.

**Flexeril 100mg #15:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**Decision rationale:** The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence (Homik, 2004). In this case, the use of a muscle relaxant is not guideline-supported. This is secondary to poor effectiveness for chronic long-term use. As such, the request is not indicated. Therefore the request is not medically necessary.

**Flurbi (NAP) Cream-LA180gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic)/NSAIDs (non-steroidal anti-inflammatory drugs).

**Decision rationale:** The request is for the use of a medication in the NSAID class. The ODG state the following regarding this topic: Specific recommendations: Osteoarthritis (including knee and hip) is recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between

traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although 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 (with Naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function (Chen, 2008), (Laine, 2008). Back Pain - Acute low back pain & acute exacerbations of chronic pain is recommended as a second-line treatment after acetaminophen. In general, there is conflicting to negative evidence that NSAIDs are more effective than acetaminophen for acute LBP (van Tulder, 2006), (Hancock, 2007). For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects (Roelofs-Cochrane, 2008). The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician (Hancock, 2007). Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another (Roelofs-Cochrane, 2008). See also Anti-inflammatory medications. Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in patients with neuropathic pain (Namaka, 2004), (Gore, 2006). See NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; & Medications for acute pain (analgesics). Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage (Maroon, 2006). The risks of NSAIDs in older patients, which include increased cardiovascular risk and gastrointestinal toxicity, may outweigh the benefits of these medications (AGS, 2009). As stated above, acetaminophen would be considered first-line treatment for chronic pain. In this case, the continued use of an NSAID is not supported. This is secondary to inadequate documentation of functional improvement benefit seen. Also, the duration of use places the patient at risk for gastrointestinal and cardiovascular side-effects. In addition, it is known that use of NSAIDs delays the healing of soft tissue including ligaments, tendons, and cartilage. As such, the request is not indicated. Therefore the request is not medically necessary.

**Gabacyclotram Cream 180gms:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The guidelines state Gabapentin: Not recommended. There is no peer-reviewed literature to support use. In this case, the use of gabapentin is not indicated for use for the patient's condition. This is secondary to poor clinical evidence of efficacy. As such, the request is not medically necessary.

**Physiotherapy low back x 6:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Physical Medicine.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Lumbar & Thoracic (acute & chronic)/Physical therapy.

**Decision rationale:** The request is for physical therapy. The ODG state the following regarding this topic: ODG Physical Therapy Guidelines, Allow for fading of treatment frequency (from up to 3 or more visits per week to 1 or less), plus active self-directed home PT. Also see other general guidelines that apply to all conditions under Physical Therapy in the ODG Preface, including assessment after a "six-visit clinical trial". Lumbar sprains and strains: 10 visits over 8 weeks; Sprains and strains of unspecified parts of back: 10 visits over 5 weeks; Sprains and strains of sacroiliac region: Medical treatment: 10 visits over 8 weeks; Lumbago; Backache, unspecified: 9 visits over 8 weeks; Intervertebral disc disorders without myelopathy: Medical treatment: 10 visits over 8 weeks; Post-injection treatment: 1-2 visits over 1 week; Post-surgical treatment (discectomy/laminectomy): 16 visits over 8 weeks; Post-surgical treatment (arthroplasty): 26 visits over 16 weeks; Post-surgical treatment (fusion, after graft maturity): 34 visits over 16 weeks; Intervertebral disc disorder with myelopathy: Medical treatment: 10 visits over 8 weeks; Post-surgical treatment: 48 visits over 18 weeks; Spinal stenosis: 10 visits over 8 weeks; Sciatica; Thoracic/lumbosacral neuritis/radiculitis, unspecified: 10-12 visits over 8 weeks; Curvature of spine: 12 visits over 10 weeks; Fracture of vertebral column without spinal cord injury: Medical treatment: 8 visits over 10 weeks; Post-surgical treatment: 34 visits over 16 weeks; Fracture of vertebral column with spinal cord injury: Medical treatment: 8 visits over 10 weeks; Post-surgical treatment: 48 visits over 18 weeks; Torticollis: 12 visits over 10 weeks; Other unspecified back disorders: 12 visits over 10 weeks; Work conditioning (See also Procedure Summary entry): 10 visits over 8 weeks. In this case, the request is not guideline-supported. This is secondary no recent acute exacerbation documented. An initial six-visit clinical trial is required and with functional improvement seen, further therapy is allowed. Functional improvement is recorded. As such, the request is not indicated. Therefore the request is not medically necessary.

**L/S Brace x 1:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment in workers Compensation (TWC), Lumbar supports.

**MAXIMUS guideline:** Decision based on MTUS General Approaches 2004, Section(s): Prevention.

**Decision rationale:** The request is for the use of a lumbar back support to aid in pain relief and injury prevention. The ACOEM guidelines makes the following statement: "The use of back belts as lumbar support should be avoided because they have been shown to have little or no benefit, thereby providing only a false sense of security." As an alternative it is advised that prolonged sitting and standing should be reduced by providing rest and exercise breaks and task rotation and variation should be employed. Heavy loads need to be divided and mechanical support devices used. Also, the workstation can be set up to optimize reduction in back strain. As such, due to poor evidence of its utility and effectiveness, the request is not indicated. Therefore the request is not medically necessary.

**Left L5-S1 Epidural Injection:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Epidural steroid injections (ESIs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Epidural steroid injections (ESIs).

**Decision rationale:** The request is for an epidural steroid injection to aid in pain relief. There are certain qualifying criteria regarding the use of this treatment modality. The MTUS guidelines state the following on this topic: Criteria for the use of Epidural steroid injections: Note: The purpose of ESI is to reduce pain and inflammation, restoring range of motion and thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit. Per the guidelines, the criteria for injections are as follows: 1) Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing. 2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants). 3) Injections should be performed using fluoroscopy (live x-ray) for guidance. 4) If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at an interval of at least one to two weeks between injections. 5) No more than two nerve root levels should be injected using transforaminal blocks. 6) No more than one interlaminar level should be injected at one session. 7) In the therapeutic phase, repeat blocks should be based on continued objective documented pain and functional improvement, including at least 50 percent pain relief with associated reduction of medication use for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year (Manchikanti, 2003), (CMS, 2004) (Boswell, 2007). 8) Current research does not support a series-of-three injections in either the diagnostic or therapeutic phase. The recommendation is no more than 2 ESI injections. In

this case, the patient does not meet the criteria set above. This is secondary to inadequate documentation of physical exam and radiographic findings of radiculopathy. As such, the request is not indicated. Therefore the request is not medically necessary.

### **Urine Drug Screen: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Drug testing. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment in Workers Compensation, Criteria for the use of Urine Drug Testing.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic)/Urine drug testing (UDT).

**Decision rationale:** The request is for a urine drug screen. The ODG states the following regarding this topic: Recommended as a tool to monitor compliance with prescribed substances, identify use of undisclosed substances, and uncover diversion of prescribed substances. The test should be used in conjunction with other clinical information when decisions are to be made to continue, adjust or discontinue treatment. This information includes clinical observation, results of addiction screening, pill counts, and prescription drug monitoring reports. The prescribing clinician should also pay close attention to information provided by family members, other providers and pharmacy personnel. The frequency of urine drug testing may be dictated by state and local laws. Indications for UDT: At the onset of treatment: (1) UDT is recommended at the onset of treatment of a new patient who is already receiving a controlled substance or when chronic opioid management is considered. Urine drug testing is not generally recommended in acute treatment settings (i.e. when opioids are required for nociceptive pain). (2) In cases in which the patient asks for a specific drug. This is particularly the case if this drug has high abuse potential, the patient refuses other drug treatment and/or changes in scheduled drugs, or refuses generic drug substitution. (3) If the patient has a positive or at risk addiction screen on evaluation. This may also include evidence of a history of comorbid psychiatric disorder such as depression, anxiety, bipolar disorder, and/or personality disorder. See Opioids, screening tests for risk of addiction & misuse. (4) If aberrant behavior or misuse is suspected and/or detected. See Opioids, indicators for addiction & misuse. Recommendations for Ongoing monitoring: (1) If a patient has evidence of a "high risk" of addiction (including evidence of a comorbid psychiatric disorder (such as depression, anxiety, attention-deficit disorder, obsessive-compulsive disorder, bipolar disorder, and/or schizophrenia), has a history of aberrant behavior, personal or family history of substance dependence (addiction), or a personal history of sexual or physical trauma, ongoing urine drug testing is indicated as an adjunct to monitoring along with clinical exams and pill counts. See Opioids, tools for risk stratification & monitoring. (2) If dose increases are not decreasing pain and increasing function, consideration of UDT should be made to aid in evaluating medication compliance and adherence. The frequency of drug testing is indicated as follows: Patients at "low risk" of addiction/aberrant behavior should be tested within six months of initiation of therapy and on a yearly basis thereafter. There is no reason to perform confirmatory testing unless the test is inappropriate or there are unexpected results. If required, confirmatory testing should be for the questioned drugs only. Patients at "moderate risk" for

addiction/aberrant behavior are recommended for point-of-contact screening 2 to 3 times a year with confirmatory testing for inappropriate or unexplained results. This includes patients undergoing prescribed opioid changes without success, patients with a stable addiction disorder, those patients in unstable and/or dysfunction social situations, and for those patients with comorbid psychiatric pathology. Patients at "high risk" of adverse outcomes may require testing as often as once per month. This category generally includes individuals with active substance abuse disorders. In this case, a urine drug screen is not supported by the guidelines. This is secondary to inadequate documentation of risk level commensurate to the frequency of evaluation requested. As such, it is not indicated. Therefore the request is not medically necessary.