

<b>Case Number:</b>	CM15-0062458		
<b>Date Assigned:</b>	05/15/2015	<b>Date of Injury:</b>	02/07/2012
<b>Decision Date:</b>	09/15/2015	<b>UR Denial Date:</b>	03/06/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/02/2015

### 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 41-year-old male, who sustained an industrial injury on 02/07/2012. He has reported subsequent low back and leg pain and was diagnosed with degeneration of lumbar/lumbosacral disc. Treatment to date has included oral and topical pain medication, chiropractic treatment, physical therapy and a home exercise program. In a progress note dated 01/23/2015, the injured worker complained of severe back and leg pain as well as intermittent weakness and reports of falling. Objective findings were notable for spasm and guarding of the lumbar spine. A request for authorization of Butrans patch on 01/23/2015 and 02/26/2015, Nabumetone-Relafen on 01/23/2015 and 02/26/2015, Orphenadrine-Norflex on 01/23/2015 and 02/26/2015, Pantoprazole on 01/23/2015 and 02/26/2015, Glucosamine Sulfate on 01/23/2015 and 02/26/2015, Escitalopram on 01/23/2015 and Gabapentin on 01/23/2015 was submitted.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective request for Butrans patch 15mcg #4, provided on date of service:**

**1/23/15, 2/26/15:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 26-27 of 127.

**Decision rationale:** The request is for the use of Buprenorphine. This is a medication, which is an opioid agonist-antagonist. It is usually used for the treatment of opioid addiction. The MTUS guidelines state the following: Treatment of opiate agonist dependence (FDA Approved indication includes sublingual Subutex and Suboxone): Recommended. When used for treatment of opiate dependence, clinicians must be in compliance with the Drug Addiction Treatment Act of 2000. (SAMHSA, 2008) Buprenorphine is pharmacological and safety profile makes it an attractive treatment for patients addicted to opioids. Buprenorphine's usefulness stems from its unique pharmacological and safety profile, which encourages treatment adherence and reduces the possibilities for both abuse and overdose. Studies have shown that buprenorphine is more effective than placebo and is equally as effective as moderate doses of methadone in opioid maintenance therapy. Few studies have been reported on the efficacy of buprenorphine for completely withdrawing patients from opioids. In general, the results of studies of medically assisted withdrawal using opioids (e.g., methadone) have shown poor outcomes. Buprenorphine, however, is known to cause a milder withdrawal syndrome compared to methadone and for this reason may be the better choice if opioid withdrawal therapy is elected. (McNicholas, 2004) (Helm, 2008) In this case, there is documentation of functional improvement with use as well as adherence to the treatment protocol with no sign of opiate abuse. As such, the request is medically necessary.

**Retrospective request for Nabumelone-Relafen 500mg #90, provided on date of service: 1/23/15, 2/26/15: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 67-68 of 127.

**Decision rationale:** The request is for the use of NSAIDS to aid in pain relief. NSAIDS are usually used to aid in pain and inflammation reduction. The MTUS guidelines states that for osteoarthritis NSAIDS 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, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDS appear to be superior to acetaminophen especially for patients with moderate to severe pain. There is no evidence to support one drug in this class over another based on efficacy. In particular, there appears to be no difference between NSAIDS and COX-2 NSAIDS in terms of pain relief. The main concern of selection is based on adverse effects, with COX-2 NSAIDS having fewer GI side effects at the risk of increased cardiovascular side effects. 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 and function. (Chen, 2008) (Laine, 2008) For back pain, NSAIDS are recommended as a second-line treatment after acetaminophen. In general,

there is conflicting 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) In this case, there is inadequate documentation of functional improvement to justify continued use, as the guidelines recommend the lowest dose for the shortest period of time. The significant side effect profile of medications in this class put the patient at risk when used chronically. As such, the request is not medically necessary.

**Retrospective request for Orphenadrine-Norflex ER 100mg, #90, provided on date of service: 1/23/15, 2/26/15: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 63 of 127.

**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) Due to inadequate qualifying evidence for use of a muscle relaxant, the request is not medically necessary. All muscle relaxant medications should be titrated down slowly to prevent an acute withdrawal syndrome.

**Retrospective request for Pantoprazole-Protonix 20mg, #60, provided on date of service: 1/23/15, 2/26/15: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 68 of 127.

**Decision rationale:** The request is for the use of a medication in the class of a proton pump inhibitor. This is usually given as an acid reducing medication for patients with esophageal reflux, gastritis, or 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 > 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 medically necessary.

**Retrospective request for Glucosamine Sulfate 500mg, #90, provided on date of service: 1/23/15, 2/26/15: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 50 of 127.

**Decision rationale:** The request is for the use of glucosamine for pain relief. The MTUS guidelines state the following regarding this topic: Recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride (GH). (Richy, 2003) (Ruane, 2002) (Towheed-Cochrane, 2001) (Braham, 2003) (Reginster, 2007) A randomized, double-blind placebo controlled trial, with 212 patients, found that patients on placebo had progressive joint-space narrowing, but there was no significant joint-space loss in patients on glucosamine sulphate. In this case, the use of glucosamine is not indicated. The patient does not meet the diagnostic criteria set for use. As such, the request is not medically necessary.

**Retrospective request for Escitalopram-Lexapro 5mg, #180, provided on date of service: 1/23/15: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 14 of 127.

**Decision rationale:** The request is for the use of a medication in the class of a selective serotonin reuptake inhibitor. The MTUS guidelines state the following regarding this topic: Low Back Pain: Chronic: A systematic review indicated that tricyclic antidepressants have demonstrated a small to moderate effect on chronic low back pain (short-term pain relief), but the effect on function is unclear. This effect appeared to be based on inhibition of norepinephrine reuptake. SSRIs have not been shown to be effective for low back pain (there was not a significant difference between SSRIs and placebo) and SNRIs have not been evaluated for this condition. (Chou, 2007) Reviews that have studied the treatment of low back pain with tricyclic antidepressants found them to be slightly more effective than placebo for the relief of pain. A non-statistically significant improvement was also noted in improvement of functioning. SSRIs do not appear to be beneficial. (Perrot, 2006) Radiculopathy: Antidepressants are an

option, but there are no specific medications that have been proven in high quality studies to be efficacious for treatment of lumbosacral radiculopathy. (Dworkin, 2007) In this case, the use of this medication is not indicated per the guidelines. Reviews have found the use of SSRIs ineffective for low back pain. There are no specific antidepressant medications that have been proven to be efficacious for lumbosacral radiculopathy. As such, the request is not medically necessary. When discontinuing SSRI's, they should be titrated down slowly.

**Retrospective request for Gabapentin 600mg, #120, provided on date of service: 1/23/15:**  
Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 & 9792.26 Page(s): 16-17 of 127.

**Decision rationale:** The request is for the use of a medication in the category of an anti-epileptic drug (AED). These medications are recommended for certain types of neuropathic pain. Most of the randomized clinical control trials involved include post-herpetic neuralgia and painful polyneuropathy such as in diabetes. There are few trials, which have studied central pain or radiculopathy. The MTUS guidelines state that a good response to treatment is 50% reduction in pain. At least a 30% reduction in pain is required for ongoing use, and if this is not seen, this should trigger a change in therapy. There also should be documentation of functional improvement and side effects incurred with use. Disease states, which prompt use of these medications, include post-herpetic neuralgia, spinal cord injury, chronic regional pain syndrome, lumbar spinal stenosis, post-operative pain, and central pain. There is inadequate evidence to support use in non-specific axial low back pain or myofascial pain. In this case, there is inadequate documentation of a condition, which would support the use of an anti-epileptic drug. The records also do not reveal functional improvement or screening measures as required. As such, the request is not medically necessary.