

<b>Case Number:</b>	CM14-0030088		
<b>Date Assigned:</b>	08/06/2014	<b>Date of Injury:</b>	10/22/1999
<b>Decision Date:</b>	09/10/2014	<b>UR Denial Date:</b>	02/20/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/10/2014

### 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. The expert reviewer is Board Certified in Anesthesia, has a subspecialty in Acupuncture & Pain Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

51y/o male injured worker with date of injury 10/22/99 with related left sided neck pain. Per progress report dated 2/6/14, he reported neck pain that radiated into the shoulder down the arm into the ulnar side of the fingers. He also complained of cervicogenic headaches. He reported on average 5-6 migraine headaches per month. He reported his average pain since last visit was 8/10 in intensity. CT scan of the cervical spine dated 6/21/13 revealed post surgical changes at C4-C5 and C5-C6 with the central canal and neural foramina at these levels not well demonstrated. There was no evidence of recurrent or residual disc disease at these levels. 2mm bulging of the disc was noted at C6-C7 without central canal or neural foraminal stenosis. The documentation submitted for review did not state whether physical therapy was utilized. He has been treated with medication management. The date of UR decision was 2/20/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Prescription of Gralise 60mg, #90:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drug (AEDs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy Drugs Page(s): 16-18.

**Decision rationale:** Per MTUS CPMTG, Gabapentin (Neurontin) has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. I respectfully disagree with the UR physician's assertion that the clinical documentation was insufficient to suspect neuropathy. As the patient had cervical fusion, it is sufficient evidence of neuropathic pain. The request is medically necessary.

**Prescription of Baclofen 10mg, #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (For Pain).

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

**Decision rationale:** With regard to muscle relaxants, the MTUS CPMTG states: Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Regarding Baclofen: It is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. As the documentation provided for review does not indicate that the injured worker has multiple sclerosis or spinal cord injury, which is the conditions for which Baclofen is recommended, the request is not medically necessary.

**Prescription of Zomig #60:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Serotonin-norepinephrine reuptake inhibitors (SSNRIs). Decision based on Non-MTUS Citation drugs.com "Zomig (zolmitriptan)" [www.drugs.com/uk/zomig-rapimelt-leaflet.html](http://www.drugs.com/uk/zomig-rapimelt-leaflet.html).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Head, Migraine pharmaceutical treatment and Other Medical Treatment Guideline or Medical Evidence: <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0001947/>.

**Decision rationale:** Per the U.S. National Library of Medicine, Zomig (zolmitriptan) is used to treat acute migraine headaches. Per ODG TWC with regard to migraine pharmaceutical treatment, recommend triptans for migraine sufferers. At marketed doses, all oral triptans (e.g., sumatriptan, brand name Imitrex) are effective and well tolerated. Differences among them are in general relatively small, but clinically relevant for individual patients. I respectfully disagree with the UR physician's assertion that the documentation does not indicate that the injured worker's headaches are considered migraine headaches. Per the most recent progress reports, multiple migraine headaches are noted monthly. The request is medically necessary.

**Prescription of Dexilant 4mg, #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG-TWC), Pain Chapter, Proton Pump Inhibitors (PPI).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & Cardiovascular Risk Page(s): 68.

**Decision rationale:** The MTUS Chronic Pain Medical Treatment Guidelines recommend the use of proton pump inhibitors in conjunction with NSAIDs in situations in which the patient is at risk for gastrointestinal events including: (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). CPMTG guidelines further specify: Recommendations: Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) Patients at intermediate risk for gastrointestinal events and no cardiovascular disease:(1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxyn plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007)As there is no documentation of peptic ulcer, GI bleeding or perforation, or cardiovascular disease in the records available for my review, the injured worker's risk for gastrointestinal events is low. Furthermore, the documentation does not indicate that the injured worker is being treated with NSAIDs, as such, medical necessity cannot be affirmed.

**Prescription of Methadone 10mg, #90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 61, 78.

**Decision rationale:** With regard to methadone, the MTUS CPMTG states: Recommended as a second-line drug for moderate to severe pain if the potential benefit outweighs the risk. The FDA reports that they have received reports of severe morbidity and mortality with this medication. This appears, in part, secondary to the long half-life of the drug (8-59 hours). Pain relief on the other hand only lasts from 4-8 hours. Methadone should only be prescribed by providers experienced in using it.Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding on-going management of opioids Four domains have been proposed as most relevant for ongoing

monitoring of chronic pain patients on opioids: Pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug related behaviors. These domains have been summarized as the '4 As' (Analgesia, activities of daily living, adverse side effects, and any aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. Review of the available medical records reveals neither documentation to support the medical necessity of methadone nor any documentation addressing the '4 A's' domains, which is a recommended practice for the on-going management of opioids. Specifically, the notes do not appropriately review and document pain relief, functional status improvement, appropriate medication use, or side effects. The MTUS considers this list of criteria for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and they do not appear to have been addressed by the treating physician in the documentation available for review. Furthermore, efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. There is no documentation comprehensively addressing this concern in the records available for my review. As MTUS recommends discontinuing opioids if there is no overall improvement in function, medical necessity cannot be affirmed.

**Prescription of Fortesta, 1 bottle: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation drugs.com.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone replacement for hypogonadism (related to opioids) Page(s): 110.

**Decision rationale:** With regard to testosterone replacement, the MTUS CPMTG states: Recommended in limited circumstances for patients taking high-dose long-term opioids with documented low testosterone levels. Hypogonadism has been noted in patients receiving intrathecal opioids and long-term high dose opioids. The documentation submitted for review reveals no documented subjective complaints or objective findings that indicate signs or symptoms of hypogonadism. Without documentation of testosterone levels or symptoms of hypogonadism, medical necessity cannot be affirmed. The request is not medically necessary.

**Prescription of Zanaflex 4mg, #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (For Pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antispasticity/antispasmodic drugs Page(s): 66.

**Decision rationale:** Per MTUS CPMTG p66 Tizanidine is a centrally acting alpha<sub>2</sub>-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. (Malanga, 2008) Eight studies have demonstrated efficacy for low back pain. (Chou, 2007) One study (conducted only in females) demonstrated a significant decrease in pain associated with

chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. Per the documentation submitted for review, the injured worker has been using this medication since at least 8/2013. It is not clear to me if the MTUS specifies that tizanadine is for short term use, however, as muscle relaxants are recommended for short-term use, the request is not medically necessary.

**Prescription of Dilaudid 4mg, #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-75, 93.

**Decision rationale:** Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding ongoing management of opioids Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: Pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug related behaviors. These domains have been summarized as the '4 As' (Analgesia, activities of daily living, adverse side effects, and any aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. Review of the available medical records reveals neither documentation to support the medical necessity of dilaudid nor any documentation addressing the '4 A's' domains, which is a recommended practice for the on-going management of opioids. Specifically, the notes do not appropriately review and document pain relief, functional status improvement, appropriate medication use, or side effects. The MTUS considers this list of criteria for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and they do not appear to have been addressed by the treating physician in the documentation available for review. Furthermore, efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. There is no documentation comprehensively addressing this concern in the records available for my review. As MTUS recommends discontinuing opioids if there is no overall improvement in function, medical necessity cannot be affirmed.

**Prescription of Duexis #60:** 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-TWC), Pain Chapter, Duexis (ibuprofen & famotidine).

**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), Duexis.

**Decision rationale:** The MTUS is silent on the use of this medication. Per ODG TWC with regard to Duexis: Not recommended as a first-line drug. Horizon Pharma recently announced the

launch of Duexis, a combination of ibuprofen 800 mg and famotidine 26.6 mg, indicated for rheumatoid arthritis and osteoarthritis. (FDA, 2012) Ibuprofen (eg, Motrin, Advil) and famotidine (eg, Pepcid) are also available in multiple strengths OTC and other strategies are recommended to prevent stomach ulcers in patients taking NSAIDs. See NSAIDs, GI symptoms & cardiovascular risk, where Proton pump inhibitors (PPIs) are recommended. With less benefit and higher cost, it would be difficult to justify using Duexis as a first-line therapy. The documentation submitted for review does not support the use of a histamine-2 blocker. Duexis is not recommended as a first-line treatment. There was no documentation of failure of trial of first line NSAIDs and PPIs. The combination medication prescribed is not reasonable unless there has been intolerance to the medications taken separately or if there is some contraindication for their use as separate medications, which has not been noted. The request is not medically necessary.

**Prescription of Flexeril 10mg, #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (For Pain).

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

**Decision rationale:** With regard to muscle relaxants, the MTUS CPMTG states: Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Regarding Cyclobenzaprine: Recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects. Per the documentation submitted for review, the injured worker has been using this medication since at least 8/2013. As muscle relaxants are recommended for short-term use, the request is not medically necessary.

**Prescription of Subsys 400ugm, #30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG-TWC), Pain Chapter, Subsys (Fentanyl Sublingual Spray).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 47.

**Decision rationale:** Per MTUS CPMTG, Fentanyl is an opioid analgesic with a potency eighty times that of morphine. Weaker opioids are less likely to produce adverse effects than stronger opioids such as fentanyl. The MTUS is silent on the use of sublingual fentanyl, however,

fentanyl buccal tablets are not recommended for musculoskeletal pain, and are currently approved for the treatment of breakthrough pain in certain cancer patients. As the MTUS does not recommend fentanyl for musculoskeletal pain, the request is not medically necessary.