

|                       |              |                              |            |
|-----------------------|--------------|------------------------------|------------|
| <b>Case Number:</b>   | CM13-0037284 |                              |            |
| <b>Date Assigned:</b> | 12/13/2013   | <b>Date of Injury:</b>       | 01/09/1998 |
| <b>Decision Date:</b> | 02/24/2014   | <b>UR Denial Date:</b>       | 09/23/2013 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 09/28/2013 |

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Pain Management, has a subspecialty in Disability Evaluation 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 physician 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:

The patient is a 61-year-old female lathe machine operator who sustained a work related injury to her upper extremities, neck and back when she attempted to stop a filing cabinet from falling. The patient underwent left shoulder surgery on 3/29/1998, neck fusion at C4-6 in May 2000, left carpal tunnel release on 3/21/2003 and a brachial plexus surgery on 4/10/2009. As per operative report dated 03/12/13, the patient underwent an inpatient anterior cervical discectomy and bilateral foraminotomy using the operating microscope. After the surgery, the patient was still complaining of being in a lot of pain, she stated that the pain was unbearable and she was not able to handle it without IV Dilaudid. On July 25, 2013 the patient received a left C6-C7 epidural steroid injection under fluoroscopic guidance; the patient states that she feels it helped improve the pain over the left posterior shoulder area. She states that the pain in that area has improved. She remains symptomatic with neck pain, headaches and left arm pain. She complains of constant pain over the cervical spine mostly in the left side. She has numbness, tingling, and pins and needles sensation in the distal left upper extremity. The patient also complains of headaches and remains symptomatic with GI symptoms and nausea. Diagnostic studies have included a cervical MRI on 8/1/12 showed fusion at C3-C7 with no evidence of solid osseous fusion, and a lumbar MRI on 6/20/12 showed degenerative disc disease at L5-S 1 with a disc protrusion and severe bilateral neuroforaminal narrowing. A urine drug screen was performed on 7/16/13 and showed consistent results.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**90 tablets of Lyrica 50 mg between 9-19-2013 and 11-3-2013: 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 Anti-Epileptic Drug Page(s): 17. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Therapy Section: Lyrica (Pregabalin).

**Decision rationale:** CA-MTUS (Effective July 18, 2009) page 17, section on Anti-Epileptic Drugs Pregabalin (Lyrica®), no generic available) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. This medication is designated as a Schedule V controlled substance because of its causal relationship with euphoria. (Blommel, 2007) This medication also has an anti-anxiety effect. Pregabalin is being considered by the FDA as treatment for generalized anxiety disorder and social anxiety disorder . Weaning: Do not discontinue pregabalin abruptly and weaning should occur over a one-week period. Withdrawal effects have been reported after abrupt discontinuation. ODG-TWC-Pain Therapy: Lyrica (Pregabalin) Recommended in neuropathic pain conditions and fibromyalgia, but not for acute pain. Pregabalin (Lyrica®) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. Pregabalin was also approved to treat fibromyalgia. See Anti-epilepsy drugs (AEDs) for general guidelines, as well as specific Pregabalin listing for more information and references. This Cochrane review concluded that pregabalin has proven efficacy in neuropathic pain conditions and fibromyalgia. A minority of patients will have substantial benefit with pregabalin, and more will have moderate benefit. Many will have no or trivial benefit, or will discontinue because of adverse events. Individualization of treatment is needed to maximize pain relief and minimize adverse events. There is no evidence to support the use of pregabalin in acute pain scenarios. (Moore-Cochrane, 2009).

**60 tablets of Prilosec 20 mg between 9-19-2013 and 11-3-2013: 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 NSAIDs, GI symptoms & cardiovascular risk Page(s): 68.

**Decision rationale:** Prilosec or PPI is recommended with precautions in patients taking NSAID, because of potential development of gastro-intestinal bleeding. According to Chronic Pain Medical Treatment Guidelines page 68 (MTUS -Effective July 18, 2009) clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (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). The patient does not fall into any of these categories, besides the subjective complaints of GI symptoms and nausea, there is

no diagnosis of gastritis, and hence the request for 60 tablets of Prilosec 20 mg between 9-19-2013 and 11-3-2013 is not medically necessary.

**90 tablets of Soma 350 mg between 9-19-2013 and 11-3-2013: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), TWC Pain Procedure Summary.

**Decision rationale:** CA-MTUS (Effective July 18, 2009) page 65, section on Antispasmodics-Carisoprodol (Soma®®, Soprodal 350mg, Vanadom®®, generic available): Neither of these formulations is recommended for longer than a 2 to 3 week period. Carisoprodol is metabolized to meprobamate an anxiolytic that is a schedule IV controlled substance. Carisoprodol is classified as a schedule IV drug in several states but not on a federal level. It is suggested that its main effect is due to generalized sedation as well as treatment of anxiety. This drug was approved for marketing before the FDA required clinical studies to prove safety and efficacy. Withdrawal symptoms may occur with abrupt discontinuation. (See, 2008) (Reeves, 2003) Side Effects: drowsiness, psychological and physical dependence, and withdrawal with acute discontinuation.

**30 tablets of Zofran 4 mg between 9-19-2013 and 11-3-2013: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Therapy section: Ondansetron (Zofran).

**Decision rationale:** CA-MTUS(Effective July 18, 2009) is mute on this topic. According to Medicinenet.com, This medication is used alone or with other medications to prevent nausea and vomiting caused by cancer drug treatment (chemotherapy) and radiation therapy. It is also used to prevent and treat nausea and vomiting after surgery. It works by blocking one of the body's natural substances (serotonin) that causes vomiting. ODG-TWC-Pain Therapy section: Ondansetron (Zofran®®): Not recommended for nausea and vomiting secondary to chronic opioid use. Therefore the 30 tablets of Zofran 4 mg between 9-19-2013 and 11-3-2013 is not medically necessary.