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| <b>Case Number:</b>   | CM14-0101497 |                              |            |
| <b>Date Assigned:</b> | 09/24/2014   | <b>Date of Injury:</b>       | 02/23/1995 |
| <b>Decision Date:</b> | 11/26/2014   | <b>UR Denial Date:</b>       | 06/19/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 07/01/2014 |

### 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 Family 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:

This is a 60-year-old female who reported an industrial injury on 2/23/1995, almost 20 years ago, to the neck, bilateral shoulders, bilateral upper extremities, bilateral hands, psych, and gastrointestinal issues. The patient has been treated with nerve blocks; injections; epidural steroid; narcotic pain medications; physical therapy; TENS unit; group therapy; psychotherapy. The patient was using a spinal cord stimulator for pain control. The objective findings on examination included no acute distress; cervical and lumbar examination appeared normal; tenderness to palpation to the cervical, thoracic, and lumbar spine; SLR negative bilaterally; normal strength and deep tendon reflexes. The treating diagnoses included lumbar spine degenerative disc disease; lumbosacral intervertebral disc disease; carpal tunnel system bilateral; fibromyalgia. The treatment plan includes the refill of medications including Oxymorphone 10 mg #90; Omeprazole 20 mg #30; Voltaren-XR 100 mg #30; and Cambia 50 mg pack #90.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Oxymorphone HCL 10mg, #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 300-306. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

chapter on pain, opioids, criteria for use American College of Occupational and Environmental Medicine (ACOEM), 2ndEdition, (2004) chapter 6 pages 114-16;

**Decision rationale:** Evidence-based guidelines recommend short-term use of opioids for the management of chronic nonmalignant moderate to severe pain. Long-term use is not recommended for nonmalignant pain due to addiction, dependency, intolerance, abuse, misuse, and/or side effects. Ongoing opioid management criteria are required for long-term use with evidence of reduce pain and improve function as compared to baseline measurements or a return to work. The patient is being treated with opioids for chronic low axial mechanical back pain. The CA MTUS Chronic Pain Medical Treatment Guidelines section on Opioids states "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects." The medical records provided for review do not contain the details regarding the above guideline recommendations. There is no objective evidence provided to support the continued prescription of opioid analgesics for the cited diagnoses and effects of the industrial claim. There is no documented sustained functional improvement. There is no medical necessity for opioids directed to chronic mechanical neck and back pain. The prescription for Oxymorphone 10 mg #90 is being prescribed as opioid analgesics for the treatment of chronic back pain and hip pain against the recommendations of the ACOEM Guidelines. There is no objective evidence provided to support the continued prescription of opioid analgesics for chronic back pain 20 years after the initial DOI. There is no demonstrated medical necessity for the continuation of Oxymorphone for chronic back pain. The chronic use of Oxymorphone is not recommended by the CA MTUS; the ACOEM Guidelines, or the Official Disability Guidelines for the long-term treatment of chronic pain and is only recommended as a treatment of last resort for intractable pain. The prescription of opiates on a continued long-term basis is inconsistent with the CA MTUS and the Official Disability Guidelines recommendations for the use of opiate medications for the treatment of chronic pain. There is objective evidence that supports the use of opioid analgesics in the treatment of this patient over the use of NSAIDs for the treatment of chronic pain. The current prescription of opioid analgesics is not consistent with evidence-based guidelines based on intractable pain. The ACOEM Guidelines updated chapter on chronic pain states "Opiates for the treatment of mechanical and compressive etiologies: rarely beneficial. Chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs (as suggested by the WHO step-wise algorithm). When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to (not substituted for) the less efficacious drugs. A major concern about the use of opioids for chronic pain is that most randomized controlled trials have been limited to a short-term period (70 days). This leads to a concern about confounding issues; such as, tolerance, opioid-induced hyperalgesia, long-range adverse effects, such as, hypogonadism and/or opioid abuse, and the influence of placebo as a variable for treatment effect." ACOEM guidelines state that opioids appear to be no more effective than safer analgesics for managing most musculoskeletal and eye symptoms; they should be used only if needed for severe pain and only for a short time. The long-term use of opioid medications may be considered in the treatment of chronic musculoskeletal pain, If: The patient has signed an appropriate pain contract; Functional expectations have been agreed to by the clinician and the patient; Pain medications will be provided by one physician only; The patient agrees to use only those medications recommended or agreed to by the clinician. ACOEM also notes, "Pain medications are typically not useful in the sub-acute and chronic

phases and have been shown to be the most important factor impeding recovery of function." There is no clinical documentation by with objective findings on examination to support the medical necessity of Oxymorphone for this long period of time or to support ongoing functional improvement. There is no provided evidence that the patient has received benefit or demonstrated functional improvement with the prescribed Oxymorphone. There is no demonstrated medical necessity for the prescribed Opioids. There is no demonstrated medical necessity for the continued prescription of Oxymorphone 10 mg #90.

**Omeprazole 20mg, #30:** 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 anti-inflammatory medications Page(s): 67-68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter--medications for chronic pain; NSAIDs

**Decision rationale:** The MTUS Chronic Pain Medical Treatment Guidelines section on anti-inflammatory medications and gastrointestinal symptoms states; "Determine if the patient is at risk for gastrointestinal events." The medical records provided for review do not provide additional details in regards to the above assessment needed for this request. No indication or rationale for gastrointestinal prophylaxis is documented in the records provided. There are no demonstrated or documented GI issues attributed to NSAIDs for this patient. The patient was prescribed Omeprazole routine for prophylaxis with Voltaren/Diclofenac. The chronic prescription of proton pump inhibitors is noted to lead to osteoporosis and decreased magnesium levels. The protection of the gastric lining from the chemical effects of NSAIDs is appropriately accomplished with the use of the proton pump inhibitors such as Omeprazole. The patient is documented to be taking Diclofenac; however, there were no documented GI risks for this patient. There is no industrial indication for the use of Omeprazole due to "stomach issues" or stomach irritation. The proton pump inhibitors provide protection from medication side effects of dyspepsia or stomach discomfort brought on by NSAIDs. The use of Omeprazole is medically necessary if the patient were prescribed conventional NSAIDs and complained of GI issues associated with NSAIDs. Whereas, 50% of patient taking NSAIDs may complain of GI upset, it is not clear that the patient was prescribed Omeprazole automatically. The prescribed opioid analgesic, not an NSAID, was accompanied by a prescription for Omeprazole without documentation of complications. There were no documented GI effects of the NSAIDs to the stomach of the patient and the Omeprazole was dispensed or prescribed routinely. The prescription for Omeprazole 20 mg #30 is not demonstrated to be medically necessary.

**Voltaren-XR 100mg, #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines ANTI INFLAMMATORY MEDICATIONS.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines anti-inflammatory medications Page(s): 67-68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter medications for chronic pain and NSAIDs

**Decision rationale:** The use of Voltaren XR 100 mg #30 is consistent with the currently accepted guidelines and the general practice of medicine for musculoskeletal strains and injuries; however, there is no evidence of functional improvement or benefit from this NSAID. There is no evidence that OTC NSAIDs would not be appropriate for similar use for this patient. The prescription of Voltaren is not supported with appropriate objective evidence as opposed to the NSAIDs available OTC. The prescription of Voltaren should be discontinued in favor of OTC NSAIDs. There is no provided evidence that the available OTC NSAIDs were ineffective for the treatment of inflammation. The prescription for Voltaren XR 100 mg #30 is not demonstrated to be medically necessary. There is no documented functional improvement with the use of the prescribed Voltaren XR 100 mg 20 years after the DOI.

**Cambia 50MG pack, #9 (PACKET):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines ANTI-INFLAMMATORY MEDICATIONS.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines anti-inflammatory medications Page(s): 67-68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter medications for chronic pain and NSAIDs

**Decision rationale:** The use of Diclofenac 50 mg or Cambia is consistent with the currently accepted guidelines and the general practice of medicine for musculoskeletal strains and injuries; however, there is no evidence of functional improvement or benefit from this NSAID. There is no evidence that OTC NSAIDs would not be appropriate for similar use for this patient. The prescription of Diclofenac is not supported with appropriate objective evidence as opposed to the NSAIDs available OTC. The prescription of Diclofenac should be discontinued in favor of OTC NSAIDs. There is no provided evidence that the available OTC NSAIDs were ineffective for the treatment of inflammation. The prescription for Diclofenac 50 mg packet #9 is not demonstrated to be medically necessary. There is no documented functional improvement with the use of the prescribed Diclofenac 50 mg 20 years after the DOI. Cambia (Diclofenac) is a non-steroidal anti-inflammatory drug (NSAID). Diclofenac works by reducing substances in the body that cause pain and inflammation. Cambia is used to treat a migraine headache attacks, with or without aura, in adults 18 years of age and older. It is not used to prevent migraine headaches. Do not use Cambia to treat a cluster headache. Cambia will only treat a headache that has already begun. It will not prevent headaches or reduce the number of attacks. Recommendation is for denial.