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| Case Number: | CM14-0156441 | | |
| Date Assigned: | 09/25/2014 | Date of Injury: | 07/31/2002 |
| Decision Date: | 10/27/2014 | UR Denial Date: | 09/12/2014 |
| Priority: | Standard | Application Received: | 09/24/2014 |

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 36-year-old male who reported an industrial injury on 7/31/2002, over 12 years ago, attributed to the performance of his usual and customary job tasks. The patient complained of pain with numbness and tingling over the neck area radiating to the upper extremity and even down to the feet. The patient complained of shoulder pain previously in the left shoulder but now also in the right shoulder. The patient reported headaches attributed to his ongoing neck pain. The objective findings on examination included good cervical spine range of motion with tenderness to palpation paracervical muscles; tenderness over the left quadrant of the abdomen to my: full extremity motion with increased weakness in the upper extremities; mood and affect appeared normal. The diagnosis was peripheral neuropathy; muscle spasm of the back; history of compression fracture the spine; chronic thoracic spine pain; neuralgia neuritis; neck pain on the left side; GERD exacerbated with NSAIDs; pain in joint shoulder region; dyspepsia; and frequent headaches.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 10/325mg, #180 with 1 refill: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM,Chronic Pain Treatment Guidelines opioids Page(s): 74-97. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter-opioids

Decision rationale: The prescription for Hydrocodone-APAP (Norco) 10/325 mg #180 with refill x1 for short acting pain is being prescribed as an opioid analgesic for the treatment of chronic pain to the neck and back for the date of injury 12 years ago for the reported diagnoses. The objective findings on examination do not support the medical necessity for continued opioid analgesics. The patient is being prescribed opioids for chronic neck/back pain, which is inconsistent with the recommendations of the CA MTUS. There is no objective evidence provided to support the continued prescription of opioid analgesics for the cited diagnoses and effects of the industrial claim. The patient is 12 years status post DOI with reported continued issues; however, there is no rationale supported with objective evidence to continue the use of opioids. There is no demonstrated medical necessity for the continuation of opioids for the effects of the industrial injury. The chronic use of Hydrocodone-APAP/Norco is not recommended by the CA MTUS, the ACOEM Guidelines, or the Official Disability Guidelines for the long-term treatment of chronic neck pain. There is no demonstrated sustained functional improvement from the prescribed high dose opioids. There is no clinical documentation by with objective findings on examination to support the medical necessity of Hydrocodone-APAP 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 Hydrocodone-APAP. There is no demonstrated medical necessity for the prescribed Opioids. The continued prescription for Norco 10/325mg, #180 with refill x1 is not demonstrated to be medically necessary.

Soma 350mg, #120 with 6 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, 128,Chronic Pain Treatment Guidelines antispasticity/antispasmodic Page(s): 66.

Decision rationale: The patient is prescribed Carisoprodol/Soma 350mg, #120 with refill x6 on a routine basis for the treatment of chronic pain and is not directed to muscle spasms on a prn basis. The CA MTUS does not recommend the prescription of Carisoprodol. There is no medical necessity for the prescribed Soma 350 mg #180 for chronic pain or muscle spasms as it is not recommended by evidence based guidelines. The prescription of Carisoprodol is not recommended by the CA MTUS for the treatment of injured workers. The prescription of Carisoprodol as a muscle relaxant is not demonstrated to be medically necessary for the treatment of the chronic back pain on a routine basis. The patient has been prescribed Carisoprodol on a routine basis for muscle spasms. There is no demonstrated medical necessity for the daily prescription of Carisoprodol as a muscle relaxer on a daily basis for chronic pain. The prescription of Carisoprodol for use of a muscle relaxant for cited chronic pain is inconsistent with the recommendations of the CA MTUS, the ACOEM Guidelines, and the

Official Disability Guidelines. The use of alternative muscle relaxants was recommended by the CA MTUS and the Official Disability Guidelines for the short-term treatment of chronic pain with muscle spasms; however, muscle relaxants when used are for short-term use for acute pain and are not demonstrated to be effective in the treatment of chronic pain. The use of Carisoprodol is associated with abuse and significant side effects related to the psychotropic properties of the medication. The centrally acting effects are not limited to muscle relaxation. The prescription of Carisoprodol as a muscle relaxant is not recommended as others muscle relaxants that without psychotropic effects are readily available. There is no medical necessity for Carisoprodol 350mg, #180.

Lidoderm patches 5%, #90 with 6 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-48, Chronic Pain Treatment Guidelines anti-inflammatory medications Page(s): 67-68, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter medications for chronic pain; topical analgesics

Decision rationale: The prescription of topical Lidoderm 5%, patches #90 with refill x6 was not demonstrated to be medically necessary and no objective evidence to support the medical necessity of the prescribed topical lidocaine for the cited diagnoses. The CA MTUS does not recommend the use of Lidoderm patches for pain control as the patches or ointment are only FDA approved for the treatment of neuropathic pain attributed to post herpetic neuralgia. The patient is being treated with Lidoderm patches for chronic back and neck pain. There is no medical necessity for the use of the Lidoderm patches for the objective findings documented on examination. The request for authorization of the Lidoderm patches is not supported with objective evidence and is not recommended as a first line treatment for the treatment of chronic shoulder pain. There is no objective evidence that the Lidoderm patches are more effective than the many available alternatives for the treatment of chronic pain. There is no objective evidence to support the use of Lidoderm patches for the stated symptoms, as there are available alternatives. There is no objective evidence to support the use of topical lidocaine for the treatment of the documented diagnoses. The applicable evidence based guidelines state that more research is required prior to endorsing the use of Lidoderm patches for the treatment of chronic pain. The prescription of Lidoderm patches is FDA approved only for post herpetic neuralgia and is not to be used as a first line treatment. The provider provides no rationale for the use of the dispensed/prescribed Lidoderm patches over the readily available medical alternatives. The prescription of the Lidoderm patches is inconsistent with evidence-based guidelines. There are no prescribed antidepressants or gabapentin to support the medical necessity of Lidoderm topical patches. Evidence-based guidelines necessitate documentation of localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica) to support the medical necessity of Lidoderm patch. The patient is not taking Neurontin, thus Lidoderm is not appropriate for the treatment of this patient. There is no objective evidence to support the use of Lidoderm patches for the continuous and daily treatment of chronic back pain. There is no current clinical documentation that indicates

that the patient has a localized area of neuropathic pain for which this medication would be medically necessary. There is no demonstrated medical necessity for Lidoderm patches or topical lidocaine ointment to treat the effects of the industrial injury. ODG identifies that Lidoderm is the brand name for a lidocaine patch produced by [REDACTED]. Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. Additionally, ODG states that topical lidocaine 5% patch/ointment has been approved by the FDA for post-herpetic neuralgia, and is used off-label for diabetic neuropathy and other neuropathic pain. It has been shown to be useful in treating various chronic neuropathic pain conditions in open-label trials. (Argoff, 2006) (ODG, Pain Chapter). There is no demonstrated medical necessity for the prescribed Lidoderm 5%, patches #90 with refill x6.

Prilosec 20mg, #60 with 6 refills: 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 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 for medications that did not include NSAIDs. Prolonged use of proton pump inhibitors leads to osteoporosis and 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 not documented to be taking NSAIDs. There are no identified GI issues attributed to the prescribed NSAIDs. 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. There is no demonstrated medical necessity for the prescription for Prilosec or omeprazole 20mg, #60 with refill x6. There is no documented functional improvement with the prescribed omeprazole.

Butalbital-Asprin-caffeine 50-325-40mg, (Unspecified quantity): 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) Pain.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 300-306, Chronic Pain Treatment Guidelines Opioids Page(s): 74-97. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) Chapter 6 pages 114-116 and on the Official Disability Guidelines (ODG) Pain chapter opioids.

Decision rationale: The patient is prescribed Fioricet/Butalbital/APAP/Caffeine # unspecified for reported headaches or pain without a nexus to the cited mechanism of injury or the ongoing treatment of the patient. The prescription for Fioricet/Butalbital/APAP/Caffeine # unspecified is being continued as an opioid analgesic for the treatment of chronic pain when opioids are being prescribed beyond the recommended time period. There is no objective evidence provided of neuropathic pain. There is no objective evidence that the patient requires more than OTC (over the counter) analgesics for the various pain complaints. The patient has been prescribed generic Fioricet/Butalbital/APAP/Caffeine # unspecified; however, the Butalbital in tablet is no longer recommended for treatment of headaches. The side effect profile of Butalbital has effectively reduced the use of this medication for headache pain. It is not currently recommended for "tension headaches." Many alternatives are readily available in the form of over-the-counter headache remedies. There is no objective evidence provided to support the medical necessity of Fioricet over the available OTC medications that also contains aspirin and caffeine. The patient could be taking Excedrin over the counter for similar relief. There is no objective evidence provided to support the continued prescription of Fioricet for headaches or for chronic back and neck pain. The patient is documented to have only tenderness to palpation on physical examination and there is no objective evidence to support more than over-the-counter analgesics for the treatment of this patient in relation to his reported headaches and residual post-operative knee and back pain. The chronic use of Fioricet is not recommended by the CA MTUS, the ACOEM Guidelines, or the Official Disability Guidelines for the long-term treatment of chronic 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 unless the pain is intractable. 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. Evidence-based guidelines necessitate documentation that 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, and the patient agrees to use only those medications recommended or agreed to by the clinician to support the medical necessity of treatment with opioids. 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." There is no demonstrated medical necessity for the prescription of Fioricet or Butalbital/APAP/Caffeine, # unspecified directed to headaches.

