

Case Number:	CM14-0155428		
Date Assigned:	09/25/2014	Date of Injury:	02/28/2005
Decision Date:	10/28/2014	UR Denial Date:	09/03/2014
Priority:	Standard	Application Received:	09/23/2014

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 55-year-old male patient who reported an industrial injury on 2/28/2005, over 9 years ago, attributed to the performance of his usual and customary job tasks. The patient is being treated for reported chronic low back pain. The patient complains of lower back pain radiating to the bilateral lower extremities. The patient is noted to be seen by psychiatrist due to chronic pain. The patient is reported to take Nucynta ER 100 mg b.i.d.; gabapentin 600 mg b.i.d. for neuropathic symptoms; naproxen b.i.d. for inflammation; omeprazole for Gastro protection; Norco 7.5/325 mg up to three per day; and Senna for opioid -induced constipation. The opioids were reported to reduces pain by approximately 30% and allow him to walk 5 to 10 minutes longer. The objective findings on examination included no acute distress; antalgic gait; uses single point cane; surgical sites to the lumbar spine are well healed; diffuse tenderness to palpation of the lumbar spine with spasms appreciated; diminished range of motion to the lumbar spine; decreased sensation to the right L4, L5, S1 dermatomes; motor examination is 5-/5. The treating diagnoses included s/p lumbar surgical intervention x4; HPN of the lumbar spine with stenosis; left S1 radiculopathy per EMG; right L4-L5 and L5-S1 radiculopathy per EMG; degenerative disc disease of the lumbar spine; chronic pain syndrome.

IMR ISSUES, DECISIONS AND RATIONALES

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

Naproxen Sodium 550mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines anti-inflammatory medications Page(s): 67-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter--medications for chronic pain and NSAIDs

Decision rationale: The use of Anaprox/Naproxen 550 mg 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 Naproxen is not supported with appropriate objective evidence as opposed to the NSAIDs available OTC. There is no provided evidence that the available OTC NSAIDs were ineffective for the treatment of inflammation. The prescription for naproxen 550 mg #60 is not demonstrated to be medically necessary.

Omeprazole 20mg capsule #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines anti-inflammatory medication Page(s): 67-69. 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 Naproxen. 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 NSAIDs--Naproxen; however, there is no identified GI issues attributed to the prescribed Naproxen. 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 omeprazole 20 mg #60. There is no documented functional improvement with the prescribed omeprazole.

Gabapentin 600mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines anti-epilepsy drugs specific anti-epilepsy drugs gabapentin Page(s): 16 18. Decision based on Non-MTUS Citation pain chapter-medications for chronic pain American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) chronic pain chapter 8/8/2008 page 110

Decision rationale: The treating physician has prescribed gabapentin 600 mg #60 to the patient for the treatment of neuropathic pain over a prolonged period of time with the documentation of efficacy noted in the ongoing clinical record. The treating physician has noted decreased pain with the use of gabapentin. There is documentation of functional improvement with the prescription of the gabapentin 600 mg. There is no objective evidence of neuropathic pain. The patient is not noted to have evidence of neuropathic pain. The patient is not demonstrated to have neuropathic pain for which Gabapentin has provided functional improvement. The gabapentin was prescribed postoperatively for surgical interventions to the lumbar spine. The treating physician has provided this medication for the daily management of this patient's chronic pain. The prescription of Gabapentin (Neurontin) is recommended for neuropathic pain; however, the ACOEM Guidelines. Gabapentin or pregabalin is not recommended for treatment of chronic, non-neuropathic pain by the ACOEM Guidelines. The ACOEM Guidelines revised chronic pain chapter states that there is insufficient evidence for the use of Gabapentin or Lyrica for the treatment of axial lower back pain; chronic lower back pain; or chronic lower back pain with radiculopathy. The CA MTUS and the Official Disability Guidelines state that there is insufficient evidence to support the use of Gabapentin or Lyrica for the treatment of chronic axial lower back pain. The prescription of Gabapentin for neuropathic pain was not supported with objective findings on physical examination. There was objective evidence that the recommended conservative treatment with the recommended medications have been provided. The use of Gabapentin/Lyrica should be for neuropathic pain. Presently, there is no documented objective evidence of neuropathic pain for which the use of Gabapentin is recommended. The prescription of Gabapentin is recommended for neuropathic pain and is used to treat postherpetic neuralgia and painful polyneuropathy, such as, diabetic polyneuropathy. Anti-epilepsy drugs (AEDs) are recommended on a trial basis (Lyrica/gabapentin/pregabalin) as a first-line therapy for painful polyneuropathy, such as, diabetic polyneuropathy. The updated chapter of the ACOEM Guidelines does not recommend the use of Lyrica or Gabapentin (Neurontin) for the treatment of axial back pain or back pain without radiculopathy. The use of Gabapentin is for neuropathic pain; however, evidence based guidelines do not recommend the prescription of Gabapentin for chronic lower back pain with a subjective or objective radiculopathy and favors alternative treatment. The request for gabapentin 600 mg #180 is not demonstrated to be medically necessary. There is no demonstrated medical necessity for gabapentin 600 mg #60 for the treatment of the patient for chronic low back pain.

Hydrocodone/APAP 7.5/325mg #90: Upheld

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

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: 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 prescription for Hydrocodone-APAP (Norco) 7.5/325 mg #90 for short acting pain is being prescribed as an opioid analgesic for the treatment of chronic pain to the back for the date of injury nine (9) years ago. The objective findings on examination do not support the medical necessity for continued opioid analgesics. The patient is being prescribed opioids for chronic mechanical low 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 nine (9) years s/p DOI with reported continued issues postoperatively; 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 back/knee pain. There is no demonstrated sustained functional improvement from the prescribed high dose opioids. 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 inconsistent with evidence-based guidelines. The prescription of opiates on a continued long-term basis is inconsistent with 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 issues. 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." ACOEM guidelines state that opioids appear to be no more effective than safer analgesics for managing most musculoskeletal 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 subacute 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 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. There is no demonstrated medical necessity for the current prescription of tramadol with Norco. The continued prescription for Norco 7.5/325 mg #90 with is not demonstrated to be medically necessary.

Nucynta R 100mg #60: Upheld

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

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 114-16; Official Disability Guidelines (ODG) Pain Chapter, Opioids.

Decision rationale: The prescription for Nucynta is being prescribed as opioid analgesics for the treatment of chronic pain against the recommendations of the ACOEM Guidelines. There is no objective evidence provided to support the continued prescription of opioid analgesics for chronic mechanical back pain. The patient is prescribed opioid analgesics nine (9) years after the DOI. There is no demonstrated medical necessity to prescribe the patient high doses of opioids. The treatment of mechanical back pain with opioids is not recommended. The patient is treated high dose opioids for the treatment of mechanical back pain; however, there is no demonstrated functional improvement and even with the cited high doses; the patient still reports pain and lack of function from his prescribed medications. The chronic use of Nucynta is not recommended by the CA MTUS, the ACOEM Guidelines, or the Official Disability Guidelines for the long-term treatment of chronic back pain and is only recommended as a treatment of last resort for intractable pain. The prescription of Nucynta is inconsistent with the recommendations of evidence-based guidelines for the treatment of mechanical back 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 subacute and chronic phases and have been shown to be the most important factor impeding recovery of function." Evidence-based guidelines recommend: Chronic back pain: Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior.

The ODG states that 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. (Ballantyne, 2006) (Furlan, 2006) Long-term, observational studies have found that treatment with opioids tends to provide improvement in function and minimal risk of addiction, but many of these studies include a high dropout rate (56% in a 2004 meta-analysis). (Kalso, 2004) There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain. (Martell-Annals, 2007) (ODG, Pain Chapter). There is no demonstrated medical necessity for the continued prescription of Nucynta 100 mg b.i.d. #60.